

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

MEDICINE STORE PHARMACY, INC.)
d/b/a RXPRESS PHARMACY,)
)
Plaintiff,)
) No. 3:14-CV-02255-M
)
AFGIN PHARMA, LLC,)
)
)
Defendant.)

TRANSCRIPT OF CLAIM CONSTRUCTION HEARING
BEFORE THE HONORABLE BARBARA M. G. LYNN,
UNITED STATES DISTRICT JUDGE
TUESDAY, SEPTEMBER 1, 2015
DALLAS, TEXAS

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P R O C E E D I N G S

(September 1, 2015)

(Court opening)

(Attorney admission)

THE COURT: Good morning. The Court has convened for purposes of conducting a claim construction hearing in Medicine Store Pharmacy, Incorporated, d/b/a for RXpress pharmacy versus AfGin Pharma, LLC.

This is a declaratory judgment action, so the roles of the parties are somewhat reversed from what I usually see. In this case, the plaintiff is trying to invalidate the patent for indefiniteness. That's all that is before the Court today. Let me make -- in terms of invalidity defenses.

Let me make a general overview comment about allow the Court has been treating issues of indefiniteness. Generally speaking, I have considered issues of indefiniteness not at a claim construction hearing but after construction when I can.

The exception to that has been if there is a term in the patent that I just can't construe. If I can't find a way to construe it, because it is not sufficiently specific, i.e., too indefinite for me to be able to do so, then I believe I have to so hold at the time of construction.

1 If I can construe the term, then I will. That
2 doesn't necessarily mean that the term is not fatally
3 indefinite, but I would take up that kind of issue after
4 construction.

5 Is that clear to everyone?

6 MR. FLAMING: Yes, Your Honor.

7 THE COURT: Okay. All right. My proposal is
8 that you each, if you wish, make a very brief overview, and
9 then I would just propose that we proceed claim by claim.

10 MR. EMERSON: That's fine here, Your Honor.

11 Shall I begin?

12 THE COURT: Okay. Yes. Thank you.

13 MR. EMERSON: Your Honor, we represent the
14 plaintiff, Medicine Store Pharmacy, doing business as
15 RXpress Pharmacy. We are a compounding pharmacy located
16 in -- in Fort Worth, have been there for many years.

17 Here's the patent-in-suit, the '734 patent, and
18 it claims methods of treating migraine headaches by using a
19 cream that has a sumatriptan solution in it, and it is
20 applied to the back of the neck in close proximity to the
21 brainstem. Actually the language is the posterior cervical
22 area in close proximity to the brainstem, which in English
23 means the back of the neck, posterior cervical area, close
24 proximity to the brainstem. As we'll discuss, the
25 brainstem is up inside of your skull, so we believe that

1 means way up high.

2 THE COURT: Is the best -- I'm in the habit of
3 making full disclosure to counsel that the Court's science
4 background is quite limited.

5 MR. EMERSON: Right.

6 THE COURT: Am I -- is the best thing for me to
7 be looking at for this purpose -- and maybe you've got it
8 in your slides here -- the exhibit to Dr. Moskowitz'
9 affidavit or declaration?

10 MR. EMERSON: Yes, Your Honor. And it is in our
11 presentation, and we'll be spending some time on that.

12 THE COURT: Okay. All right.

13 MR. EMERSON: Okay. So another important thing
14 here is that the claims at issue are method claims, and so
15 this is going to be an indirect infringement case. We
16 don't actually apply the -- the cream or treat the
17 headache. We sell -- we compound and we sell the cream,
18 which is a prescription treatment. We sell those to
19 patients. So we get a prescription from a doctor, we fill
20 the prescription, we sell it to the patient. So because
21 this is a method claim, ultimately this is going to be an
22 indirect infringement case.

23 THE COURT: Let me back up for just a minute,
24 Mr. Emerson, and make sure I understand that.

25 The technical aspects of this don't matter that

1 the question that I'm asking. But what kind of
2 prescription are you getting? What kind of prescription is
3 your client getting that it is compounding? Is it getting
4 a specific prescription from a physician for a topical
5 cream comprised of blah, blah, blah or what?

6 MR. EMERSON: Yes. If you'll take a look at
7 your screen, this is the accused method. And we have
8 preprinted prescription pads. And there are a number of
9 drugs on here.

10 THE COURT: Okay. And the physicians -- I
11 remember the issue of the patent. So the physicians have
12 the pad?

13 MR. EMERSON: They have the pads.

14 THE COURT: And so it's up to them to check Box
15 A, Box B?

16 MR. EMERSON: That's right.

17 THE COURT: Okay.

18 MR. EMERSON: Occasionally, the physicians will
19 mark this up. You'll see that there's a particular
20 formulation, 5 percent sumatriptan, 2 percent tramadol, et
21 cetera, et cetera. Occasionally the doctors will mark that
22 up and change it to their preference. But always -- and
23 this is just a convenience for the doctor. It's something
24 that -- we have reps that go see doctors, and they hand out
25 prescription pads. And these pads are a -- a convenience

1 for the doctor and allows them simply to use the pad if
2 they want. They can mark it up if they want as well.

3 And so key here is the instruction at the
4 bottom. And this is our -- our pad that's no longer in
5 use. And it says "apply one click to the temples, one
6 behind the ears, and two to the base of the neck." When we
7 talk about click -- and this is not an issue, but it's like
8 a syringe that has clicks.

9 Now, one thing I want to note, and that is in
10 AfGin's opening brief -- I'm sure this was just a
11 mistake -- but it says in the opening brief that our pads
12 say, quote, "apply to the back of the neck." And our pads
13 say "apply to the base of the neck." And this will be an
14 issue in the case, Your Honor, because we'll talk about
15 what "posterior cervical area in close proximity to the
16 brainstem" means. And regardless, we think that can't mean
17 at the very bottom of your neck. But that's going to be an
18 issue.

19 THE COURT: Okay. And is your name pronounced
20 Chiarizio?

21 MR. CHIARIZIO: Yes, Your Honor, Chiarizio.

22 THE COURT: I'm sorry. Say again.

23 MR. CHIARIZIO: Chiarizio.

24 THE COURT: So when we talk about the hairline,
25 you're going to have Mr. Chiarizio up here to talk about

1 the --

2 MR. EMERSON: Yes, Your Honor. He can be one of
3 our examples. I have a sharpie and we're going to use
4 that.

5 THE COURT: I'm sorry. I just -- I couldn't
6 resist. Temptation was too great.

7 MR. EMERSON: That has come up to us as well.

8 And, Your Honor, that's, I think, a lot of the
9 case in a nutshell. The technology is, so to speak, the
10 sumatriptan formulation is put into a cream, the cream is
11 applied to the back of the neck, the temples, behind the
12 ear. Those are our instructions. That's the issue --
13 that's the accused infringement, that we're instructing our
14 ultimate patients to apply it in this way. And in that
15 way, we are inducing or contributing to their direct
16 infringement.

17 Today we have no issues regarding the chemical
18 make-up or anything like that. It's really more -- some of
19 the less technical aspects of the case.

20 So unless you have any questions, I'll let
21 Mr. Flaming speak.

22 THE COURT: Okay. Thank you.

23 MR. FLAMING: Thank you, Your Honor.

24 How do we move to --

25 THE COURT: Oh, I can do it. I'm sorry. That's

1 my job, and I'm not doing it.

2 MR. FLAMING: So this overviews how I would
3 normally do my presentation. Obviously I will handle it
4 however you want, but this is kind of the way we tend to
5 go.

6 THE COURT: Let me just make sure that I am not
7 recalling something incorrectly.

8 I haven't realigned you, have I?

9 MR. FLAMING: Not yet.

10 THE COURT: Okay. Because the plaintiff's
11 booklet refers to you as the defendant. Wishful thinking.
12 You might get your wish soon.

13 MR. EMERSON: Your Honor, that was a mistake.
14 We actually just fixed it. We were kind of chuckling about
15 that a minute ago. As I stood up, I said, "Wait a minute.
16 This says defendant. We're the plaintiffs." We feel like
17 defendant, right, because we're the accused infringer, but
18 actually we're the plaintiffs.

19 THE COURT: Well, that's what I thought. That's
20 why I made that comment at the beginning, but I've been
21 looking at the wrong books.

22 MR. EMERSON: I'll pop back. The version on
23 your screen says we're the plaintiff.

24 THE COURT: I'm sorry, Counsel. Go ahead. I'm
25 sorry. I just wanted to make sure I had the correct book

1 in front of me.

2 MR. FLAMING: That's fine.

3 So generally the way we're going to do this, the
4 way I have my slides organized is, I'm starting right now
5 as requested with a brief overview, and then I wanted to
6 highlight a few points in the law, just a couple of slides.

7 THE COURT: Okay.

8 MR. FLAMING: And then for each term in dispute,
9 my slides explain our position, and I address each one of
10 RXpress' arguments, and so hopefully we've got them all
11 covered. And if any questions come up, hopefully I've got
12 them answered in the slides. But if you have any more
13 questions, I'll be happy to answer those.

14 So the technology here is there's a patent. And
15 the patent is a topical therapy for migraine. And at a
16 high level, it's not -- it's a fairly straightforward
17 invention. Dr. Ronald Aung-Din, who is a neurologist in
18 Sarasota, Florida, was experimenting, and he discovered
19 that you -- when you have a migraine, it's a very bad
20 thing. You start to feel tingling in the back of your
21 neck, and then a whole bunch of other symptoms follow,
22 which generally, as he will say it, comes from what he
23 calls the migraine generator. It's very technical, but
24 it's a set of nerves.

25 And there are different ways to deliver the drug

1 sumatriptan, one of which is to deliver it orally so it has
2 to go through the stomach, liver, blood, and it takes time
3 and not all of it gets there.

4 So he thought, well, what if I put it directly
5 on the area that's affected, the head. And eventually he
6 narrowed that down to the very back of the neck. And he
7 said, if I put this into a formulation, it immediately
8 releases the drug -- it's not a delayed release -- the drug
9 will then hit the nerves which are right underneath the
10 skin and send a signal to stop the nerve from -- the nerve
11 complex from going crazy, which is what is causing the
12 migraine.

13 And so he discovered this would be easier
14 administrator of the drug, faster relief, it doesn't have
15 to go into the whole system of the body, and it avoids a
16 number of side effects from that way of delivery.

17 And so I'm just highlighting a couple of things
18 from his declaration in the prosecution history. He did a
19 study where he said, "I'm going to figure out where is the
20 best place to put this cream."

21 THE COURT: I'm happy for you to walk me through
22 this as you have. I've read his declaration.

23 MR. FLAMING: Okay. Then I'll just walk you
24 through quickly.

25 So basically you understand what he did. He

1 tried it on the forehead, and he tried it on the back. And
2 as the study -- keep going. I'll go to the next one --
3 there it is. The study found that, as you've read, a
4 hundred percent of the people, back of the neck, got relief
5 within 15 minutes and complete relief within an hour.

6 So that's basically the technology. And so the
7 disputes here are really not over the technology so much
8 itself as much as the location of applying the cream. I
9 think the biggest dispute between the parties is the
10 "posterior cervical area" term. And so we can address
11 that. And I think his declaration will become very
12 important as we get into that term.

13 And unless you have any other questions, that's
14 just an overview.

15 Let me just run through a couple of points of
16 law real quick. I have them listed here. I don't think
17 there's a dispute between the parties as to the law. I
18 didn't see one in the briefs. We all recognize that you
19 look at the written instruments; that the terms are read in
20 context of the patent; that the specification of the patent
21 is always relevant and the single best guide; that the file
22 history is a part of the record and is part of the
23 intrinsic record the Court considers; that if the inventor
24 uses a term in an unusual way, the inventor's use governs;
25 and that the Court should not look beyond the intrinsic

1 record unless there is a genuine ambiguity to be resolved.

2 And next -- next slide.

3 There are three points on indefiniteness that
4 we want to highlight. The standard now is reasonable
5 certainty, as you know. And Courts have recognized that
6 absolute precision is unattainable and that an important
7 fact here or principle of law here is that the law doesn't
8 require greater certainty than the technology at issue
9 requires. So we're not talking in this case about
10 machining a part to an incredibly detailed specification.
11 We're talking about applying a migraine cream on the back
12 of the head or the neck. And so this is an important
13 point.

14 Also, as you know, clear and convincing evidence
15 is the standard. To knock out a patent for indefiniteness,
16 requires a higher degree of proof.

17 And I like this, so it's my last one. The
18 standard is so exacting, even if it's hard to construe a
19 claim, and even if judges at the Federal Circuit will, as
20 they often do, disagree over the meaning of a term, that's
21 not enough to render is indefinite. It has to not be
22 reasonable certain after reading the whole record to one of
23 skill in the art.

24 And that's all I have for an overview, unless
25 you have any questions.

1 THE COURT: All right. And I'm assuming no one
2 is claiming that there are fact questions here that are
3 implicated by -- I like to call it the Teva Pharmaceuticals
4 case, but everybody else in the world who doesn't live in
5 Texas is calling it Teva. And it was pointed out to me
6 that I was wrong by asking me if I called my shoes Tevas,
7 and I said yes. So I'm not sure whether it's Teva or Teva
8 (pronouncing). But you know the case that I'm referring
9 to.

10 Are there fact questions for me in this
11 construction today?

12 MR. FLAMING: From our perspective, I would say
13 no, because I believe that all of the issues are addressed
14 in the intrinsic record and there's no need to go outside
15 of the intrinsic record. I'm not sure if counsel for
16 RXpress' would have a different perspective, but that's our
17 perspective.

18 THE COURT: Let me ask you one other general
19 question.

20 You don't have any evidence in the record,
21 unless I've missed it, about who is a person of ordinary
22 skill in the art here.

23 MR. FLAMING: The only evidence we have is the
24 declaration of Dr. Ron Aung-Din, who is himself a
25 neurologist and has the background.

1 So I don't think we have a dispute over the
2 person of ordinary skill in the art with RXpress other than
3 we believe it's somebody who has experience at least with
4 working with topical formulations. And Dr. Aung-Din does.

5 THE COURT: Well, but the question here has to
6 be how would a person of ordinary skill in the art construe
7 the term, if the term is not otherwise defined in the
8 patent, including the specifications. And I don't think
9 that the inventor's declaration, which was produced in the
10 middle of the prosecution of the patent -- I don't mean
11 that temporally -- but while the prosecution was ongoing,
12 necessarily establishes how another person -- which I think
13 a person of ordinary skill in the art is not looked at from
14 the inventor's perspective, although the inventor could
15 opine about who a person of ordinary skill in the art is.
16 So I have -- we'll get to this in more detail, I think, as
17 we go.

18 But I have Dr. Moskowitz saying this is a person
19 of ordinary skill in the art, and his conclusion about who
20 a person of ordinary skill in the art, did not seem
21 unreasonable to me. I don't know if you agree with it or
22 you disagree with it, just who is that person. Just for
23 the record, to repeat it, he says, in Paragraph 7 of his
24 declaration, a doctor -- I'm paraphrasing this -- a person
25 who has an M.D., a D.O. or a pharmacy degree, and who is a

1 doctor or a pharmacist and someone who has practical -- let
2 me stop for a moment.

3 Mr. Emerson, do you interpret or advocate that
4 Paragraph 7, the sentence beginning "additionally" means a
5 doctor or pharmacist who also has these experiences in
6 neurology?

7 Paragraph 7.

8 MR. EMERSON: Paragraph --

9 THE COURT: 7 of the Moskowitz declaration.

10 MR. EMERSON: Well -- just a moment, Your Honor.

11 THE COURT: I don't know if he means it's either
12 a doctor or a pharmacist or a person who has done research
13 or taught in neurology, et cetera, or a doctor or
14 pharmacist who also has those experiences.

15 MR. EMERSON: We think it -- we use
16 "additionally" to mean "and," so this person would also
17 have this experience.

18 THE COURT: Because it would be very unusual for
19 a pharmacist to have those experiences. It would not be
20 unusual for a physician, but it would be unusual for a
21 pharmacist to have --

22 MR. EMERSON: Well, neuropharmacology, that's
23 one of the areas --

24 THE COURT: Well, all right. That's fine. So
25 that's the person -- you can sit down, Mr. Emerson.

1 So that's the person of ordinary skill in the
2 art as Dr. Moskowitz proffers it to the Court.

3 And it that definition something that you accept
4 as a starting point?

5 MR. FLAMING: We don't disagree in general that
6 the definition covers a person of ordinary skill in the
7 art, except we believe that there is -- in answer to the
8 Court's questions, we have no other expert declarations
9 submitted as to the definition of a person of skill in the
10 art. So if that's your question, the answer is no, we
11 don't.

12 But we submit that the patent is entitled
13 "Topical therapy for migraine" and each claim calls for
14 topical administration. And so that is, from our
15 perspective, evidence that a person of ordinary skill in
16 the art would at least have some background in topical
17 formulations.

18 I mean, if you think about it --

19 THE COURT: That's fine. I don't have any
20 problem with that. It's just that the Moskowitz
21 declaration, in effect, says -- we'll get to it. I'm not
22 attempting to push us where we haven't yet gotten to. But
23 he's basically saying, okay, a person with these skills and
24 experiences who reads the patent cannot tell where the
25 formulation is to be applied on the back of the neck.

1 That's basically the lens through which I would be viewing
2 it if I followed that interpretation.

3 And in response to that, I have the inventor,
4 who is making clear what he invented, but I'm trying to
5 figure out if that means that I'm applying some different
6 lens to reviewing it from your perspective than the one
7 suggested by Dr. Moskowitz.

8 MR. FLAMING: Fair enough. I think I understand
9 where you're going with this.

10 The question is you're not a person of ordinary
11 skill in the art and neither am I. How do we know how what
12 that person would read the patent to mean.

13 And as we get to the "posterior cervical area"
14 term, for example, our position would be that the inventor,
15 who is clearly smack dab within the middle of this
16 definition of person of skill in the art -- Dr. Aung-Din is
17 a very experienced neurologist and has not only research
18 and study background, but also has background in topical
19 formulations.

20 He -- when you go to the patent office, you're
21 negotiating with a patent examiner. His interactions with
22 the patent examiner and submissions, as well as the patent
23 language itself, is itself evidence of how one of skill in
24 the art would talk basically. This is what a person of
25 skill in the art would say, and at least it's a starting

1 point.

2 As we get to talk about the lens through which
3 their expert is viewing the patent, our position is that
4 putting aside -- that the patent itself is not -- and the
5 prosecution history are not ambiguous at all as to what the
6 inventor meant by the "posterior cervical area" term.
7 There is no lack of clarity in the record. There are no
8 inconsistencies that tell the opposite. So there's no
9 need -- it's very easy to read the patent and prosecution
10 history and see what it means.

11 And I have a series of slides that show that,
12 and I also address each one of the alleged inconsistencies
13 to the point where we think there is clear and convincing
14 evidence, but it's the opposite direction, that the term is
15 extremely clear.

16 And by way of preview, what the inventor meant,
17 as he said in his declaration is -- he uses the shorthand,
18 called BONATH, "back of the neck at the hairline," as you
19 see from the declaration throughout. And he defines
20 specifically what he means by "back of the neck at the
21 hairline," which is on the skin from behind the C1 to C4
22 vertebrae. It's very clear, it's in his declaration
23 multiple times, and there's no ambiguity as to what he
24 meant. So A person of skill in the art would see that and
25 have no trouble understanding it.

1 And I'll address that more when we get to that
2 term.

3 THE COURT: Okay. All right.

4 MR. FLAMING: Thank you.

5 THE COURT: Okay. Thank you.

6 MR. EMERSON: Let me just start off by saying
7 that I agree wholeheartedly with Mr. Flaming that the term
8 "posterior cervical area" is very clear. In English,
9 again, it means back -- posterior meaning the rear;
10 cervical meaning the neck -- posterior cervical area.

11 These claims started off in 2002 -- and we'll
12 get into this in a few minutes -- just with "posterior
13 cervical area," where they talked about an area on the back
14 of the neck, or on the neck at all. They talked about
15 posterior cervical area. It wasn't in the 2008 that they
16 added the limitation of "in close proximity to the
17 brainstem." It's not entirely clear why they did that, but
18 they did.

19 And so when he says there's really no dispute
20 about "posterior cervical area," we agree. The posterior
21 cervical area is the back of the neck. It goes from the
22 top to the bottom, and there you go.

23 It's "in close proximity to the brainstem" where
24 we have the issue. And that issue is, number one, it
25 doesn't really make sense, given where the brainstem is.

1 And so for that reason, we think this term is indefinite.

2 Number two, we don't believe that the -- their
3 proposed construction is correct, because the proposed
4 construction, as we'll get into later, the back of the neck
5 at the hairline, or BONATH, was repeatedly referred to
6 simply as the back of the neck or the posterior cervical
7 area. Again and again and again, the inventor and his
8 lawyers, in prosecution, equated the terms "posterior
9 cervical area," or back of the neck, with BONATH. Never,
10 Your Honor, did the inventor or his attorneys during
11 prosecution equate BONATH with "posterior cervical area in
12 close proximity to the brainstem."

13 And so if Your Honor is not inclined to find
14 that this term is indefinite, we have an alternative
15 construction, which is based on just the basic human
16 anatomy, where the brainstem is and where it interacts with
17 the neck, if at all. And our construction is, to put it in
18 English, at the very top of the neck.

19 And so when they say "posterior cervical area in
20 close proximity to the brainstem," we read that in English
21 to mean at the back of the neck as high up as possible.
22 And as high as possible is at the C1 vertebra. Your neck
23 vertebrae go from C1 to C7; C7 being the lowest; C1 being
24 the highest. And that's where we would urge Your Honor to
25 construe the claim, if you're not inclined --

1 THE COURT: And the point of that is that above
2 that, speaking vertically, is the head.

3 MR. EMERSON: Yes, Your Honor.

4 And so with that introduction, we'll get into
5 this. Here is the claim term in dispute right now.

6 THE COURT: Stay there a minute, Mr. Emerson.

7 Mr. Flaming, can you give me any explanation for
8 why this was added in 2008?

9 MR. FLAMING: Yes, Your Honor.

10 Originally, the patent, the inventor was --
11 wanted to get the claims that covered the entire head, and
12 in the process of negotiating with the patent examiner, he
13 chose to narrow the claims, and he chose to narrow them in
14 part because he believed that this is really the only place
15 that it really works. And you see from his declaration
16 that that's the case.

17 So as often happens in prosecution, the inventor
18 narrows the scope of the patent. And the words "in close
19 proximity to the brainstem" were added to specify a portion
20 of the posterior cervical area, which would be the entire
21 back of the neck. And as -- I will -- I don't want to --

22 THE COURT: Well, let me -- I'm just going to
23 ask you one question, and the record isn't going to be very
24 clear, because I'm pointing at my own neck here.

25 If I'm over here close to my ear --

1 MR. FLAMING: Uh-huh.

2 THE COURT: -- is that the back of the neck in
3 close proximity to the brainstem?

4 MR. FLAMING: Okay. Good question. So where do
5 we draw the line, according to what we read the patent and
6 the specification?

7 And if we're talking about behind the ear, right
8 here on this bone, that would not be what I consider,
9 according to what we read, the posterior cervical area;
10 it's not the neck. But if you go down here lower behind
11 the ears, that is posterior cervical area. It's not just
12 the very back of the neck.

13 THE COURT: Okay. I don't think that you would
14 have a disagreement with Mr. Emerson that if we were just
15 talking about the posterior cervical area, that it would
16 cover all the way over to your ears. That's what a
17 layperson would think of as the back of the neck.

18 But my question is, if I'm over here below my
19 ear at my hairline, assuming that's not -- that's an
20 understandable term, is that in close proximity to the
21 brainstem?

22 MR. FLAMING: The words "in close proximity to
23 the brainstem" were added by the inventor to specify his
24 specific area. So it would be -- if you were underneath
25 your ear, right here, that's jaw. That's not neck.

1 If you are behind the ear, you can feel you
2 start feeling neck, that is what is part of the posterior
3 cervical area.

4 THE COURT: Okay. That's not my question.

5 MR. FLAMING: Okay.

6 THE COURT: I think that Mr. Emerson would
7 concede that's the posterior cervical area. What I'm
8 asking you is, is that in close proximity to the brainstem?

9 MR. FLAMING: That, by the hairline on the neck
10 back on this side, yes, would be in close proximate to the
11 brainstem as the inventor is using the term. That's what
12 he means.

13 THE COURT: Well, if that was the case, what
14 does that -- how does that phrase narrow the claim as it
15 existed before it was added?

16 MR. FLAMING: Okay. The phrase does not cover
17 the bottom of the neck. I think that's where we disagree.
18 We're drawing a line at which vertebrae. There are seven
19 in the neck. And we think the inventor only fairly claims
20 C1 to C4. That's where he says that the nerves you're
21 trying to reach are. So it would not be the bottom of the
22 neck. It would be toward the top, but we go down two more
23 vertebrae than they do.

24 THE COURT: All right. Okay. Thank you.

25 MR. EMERSON: Just to it's clear -- I thought I

1 heard you say -- maybe I heard this wrong -- that I
2 wouldn't contest that behind the ears --

3 THE COURT: No, I didn't say that.

4 MR. EMERSON: Okay.

5 THE COURT: And correct me if I'm wrong. I
6 wasn't saying behind the ear. I was saying that below the
7 ear to the side of your neck, but still close to the back
8 of your neck, you would concede is the posterior cervical
9 area. Maybe not. Maybe as it reaches the curve of your
10 neck, you would say that's not the back of your neck;
11 that's the side of your neck.

12 MR. EMERSON: I think if you went down, around
13 enough behind your ear, then yes, Your Honor, that would be
14 the back of the neck, posterior cervical area.

15 THE COURT: Okay.

16 MR. EMERSON: All right. So we don't dispute --

17 THE COURT: I mean, the real issue here is --
18 and this is the way it's going to go, as you know,
19 Mr. Emerson.

20 MR. EMERSON: I understand.

21 THE COURT: The real question, to me -- you
22 might have some marginal difference about "posterior
23 cervical area." The real crux of dispute here is "in close
24 proximity to the brainstem."

25 MR. EMERSON: Yes, Your Honor. Yes, Your Honor.

1 THE COURT: And I don't think you-all are
2 disputing -- I don't think you're disputing, because it's a
3 matter of anatomy, what's the brainstem, and you're not
4 really disputing the "posterior cervical area." The phrase
5 that is at the crux of the dispute is "in close proximity."

6 MR. EMERSON: And what does that mean and was it
7 defined. And if it wasn't defined, how should we define
8 it, based on basic human anatomy.

9 THE COURT: You don't dispute that this diagram
10 which was attached, I think, as Exhibit B to Dr. Moskowitz,
11 is inaccurate anatomy, do you, Mr. Flaming?

12 MR. FLAMING: No, I don't. In fact, I used it
13 in my slides.

14 THE COURT: Right. Okay.

15 MR. EMERSON: So we anticipated your question,
16 Your Honor, what portion of the back of the neck is in
17 close proximity to the brainstem. And based on the plain,
18 ordinary meaning of the words and basic human anatomy,
19 nothing on the back of the neck is in close proximity to
20 the brainstem. We think that the term itself is
21 intrinsically unclear and confusing and contradictory,
22 because nowhere on the back of your neck is close to your
23 brainstem.

24 THE COURT: And that conclusion -- I'm sorry. I
25 may not be using the correct terminology -- but that

1 conclusion essentially goes to the depth of the brainstem
2 within your skull measured against the surface of your
3 skin.

4 MR. EMERSON: Well, the depth and the height.
5 And so I've blown up the figure. This is from Stedman's
6 Medical Dictionary. And the brainstem is made up of the
7 midbrain, which is up at the very top of -- so the green
8 area is the brainstem.

9 THE COURT: You agree with that also, don't you,
10 Mr. Flaming?

11 MR. FLAMING: Roughly, yes. I don't have a --

12 THE COURT: Okay. And I'm going to interrupt
13 you again for a minute, Mr. Emerson. I think that you-all
14 are also in agreement that if I went above the red line --
15 it probably would be a good idea to mark this as an exhibit
16 to the hearing transcript, just so if there's an appeal
17 that people know what I'm referring to.

18 MR. EMERSON: Certainly.

19 THE COURT: Do you have a color copy of that?
20 And I'll permit you to substitute that later.

21 MR. FLAMING: Your Honor, if I may make an
22 objection. I don't know if counsel will agree or the Court
23 will, but the last four or five Markman hearings, we've
24 just submitted after the hearing the PowerPoint
25 presentation to the Court and filed it so it's part of the

1 record.

2 THE COURT: I have no problem with that if
3 you'll give me a page number of that that you're referring
4 to. What page is that?

5 MR. CHIARIZIO: This is Page 11.

6 THE COURT: Okay. So I think that you-all would
7 concede that if I went above the red line, that I would be
8 at the head and no longer at the neck?

9 MR. EMERSON: Yes, Your Honor.

10 THE COURT: You agree with that, Mr. Flaming?

11 MR. FLAMING: Yes, Your Honor.

12 THE COURT: All right. So just -- the point
13 you were making a minute ago, Mr. Emerson, was the top of
14 the neck is below -- if I'm looking at this profile view of
15 a person's head and neck, is below in a vertical dimension,
16 the bottom of the brainstem.

17 MR. EMERSON: Yes, Your Honor.

18 THE COURT: And the neck is separated from the
19 brainstem, the horizontal relationship, but the distance
20 between the back of the neck and the spine --

21 MR. EMERSON: Yes, Your Honor, right. And
22 there's skin, there's other tissue, there's the -- the
23 vertebrae, there's the occipital bone of the skull, which
24 is at the bottom of the skull. Up higher, there's brain
25 tissue between the -- the brainstem and the back of the

1 neck. So there's a lot --

2 THE COURT: Okay. But if I'm just looking at --
3 if this were the question. This isn't precisely the
4 question. But if this were the question: "What portion of
5 the neck is the closest to the brainstem?" it would be the
6 top of the neck?

7 MR. EMERSON: Absolutely. That is our position.
8 To the extent that you can construe this claim -- this
9 claim term, the construction is in English terms, back of
10 the neck at the very top. Because the brainstem is in your
11 skull. And so the closest part of your neck to the
12 brainstem is the very top of the neck.

13 THE COURT: And in this -- in this diagram, are
14 the vertebrae between -- those objects between the neck and
15 the spine?

16 MR. EMERSON: Yes, Your Honor, on either side of
17 the spinal cord. You can see the spinal cord is in
18 yellowish and then sort of --

19 THE COURT: But I want to follow up on what
20 Mr. Flaming said a minute ago.

21 Did you say C1 to C4?

22 MR. FLAMING: That's correct, Your Honor.

23 THE COURT: So you're -- you're telling me,
24 Mr. Flaming, that if I count down vertebrae, I'm going to
25 go roughly halfway down the diagram?

1 MR. FLAMING: That's right.

2 THE COURT: And you're going to argue to me in a
3 minute -- thank you.

4 Are you doing that, Mr. Emerson?

5 MR. EMERSON: I am. I'm trying my best.

6 THE COURT: Good. Now, this isn't going to show
7 on the record, but for these purposes, it's fine. So
8 halfway down -- you're going to argue to me -- not now,
9 Mr. Flaming, but in a few minutes -- that where Mr. Emerson
10 has drawn that line, which I think is at the bottom of C4,
11 is in close proximity to the brainstem?

12 MR. FLAMING: As the patent uses the term, yes.

13 THE COURT: Okay. I'm interested in that, and I
14 want --

15 MR. FLAMING: That's a very important
16 distinction. That's why I'm emphasizing that.

17 THE COURT: Okay. And you're going to tell me,
18 Mr. Emerson, that the whole concept doesn't make any sense,
19 the brainstem is deep in your brain and it's separated a
20 long distance horizontally from the back of your neck, so
21 the concept doesn't make sense, but, Judge, if you -- if
22 you conclude it does make sense it has to at least be the
23 top, C1 only, C1?

24 MR. EMERSON: Or C2. I think our brief that
25 we've made -- Dr. Moskowitz might have said C1 and C2 form

1 the junction. So C1 -- and you can see that C1 on the --
2 on the anterior side, meaning the forward side, C1 and C2
3 sort of overlap. On the rear side, yes, we would say C1,
4 which is the first one up there -- let me see if I can do
5 this again, draw a line.

6 THE COURT: Yeah. That's what I -- that's what
7 I --

8 MR. EMERSON: That's C1 -- that's C1 at the back
9 of the neck. I'm not very good at this.

10 THE COURT: Well, I just --

11 MR. EMERSON: But you're right. That's our
12 proposed construction, is the very top of the back of the
13 neck, which would be C1.

14 THE COURT: All right.

15 MR. FLAMING: And, Your Honor, if it would
16 help -- I apologize for interrupting. One of my slides
17 actually has -- I counted them out -- I don't think we'll
18 disagree as to --

19 THE COURT: Okay. All right. Thank you.

20 MR. EMERSON: Another thing we disagree with is
21 that the patent itself defines the term "in close proximity
22 to the brainstem." We hear that the patent uses the term
23 in a particular way, which we would respectfully submit
24 that it does not. But this particular way, I think,
25 conflicts with common sense.

1 When the brainstem is inside your skull, "in
2 close proximity to the brainstem" is going to be on your
3 neck, as high up as possible. Nowhere in the specification
4 do they define the term "in close proximity to the
5 brainstem." They use the term. They don't define it. And
6 as we'll talk about in a few minutes, in Dr. Aung-Din's
7 declaration, he doesn't either.

8 THE COURT: He doesn't what?

9 MR. EMERSON: He doesn't define "in close
10 proximity to the brainstem."

11 THE COURT: Of course he's in a different
12 context than we are now.

13 Dr. Moskowitz -- I'm not being critical. He's
14 writing the patent examiner, and Dr. Moskowitz is writing
15 to me. So the context is different.

16 MR. EMERSON: Right. And let me touch on that
17 for a second. After we spent a lot of time on the briefing
18 and criticizing us for using Dr. Moskowitz' declaration --
19 really the only thing we're using it for, for the most
20 part, is just to explain the anatomy. He explains the
21 anatomy using the exhibits, the Gray's Anatomy and
22 Stedman's, et cetera, and he explains where the brainstem
23 is, where it meets with the spinal cord and the anatomy of
24 the human brain and the spine, the cervical spine and the
25 spinal cord. And there's really no dispute about that.

1 There's no dispute -- as Your Honor nailed down
2 a few minutes ago, there's no dispute about where the
3 brainstem is, where it starts, where it finishes, where the
4 skull is, where the cervical spine is, et cetera. So
5 that's really the -- that's really all we're using his
6 declaration for.

7 And that -- to say given where the brainstem is
8 and given its relation to the neck, the term itself doesn't
9 make any sense. But if we were to construe it, we would
10 construe it at the top of the neck.

11 So the patent goes -- discusses a number of
12 different examples of his tests, his clinical trials, and
13 describes a lot of places to apply this cream on the back
14 of the neck. BONATH, or back of the neck at the hairline,
15 doesn't appear in the specification anywhere. This comes
16 from Dr. Aung-Din's declaration that he submitted in
17 support of his claims and also in certain arguments that
18 the patent lawyer made referring to Dr. Aung-Din's
19 declaration.

20 THE COURT: I'm sorry. Go back for a moment,
21 please.

22 Okay. Thank you.

23 MR. EMERSON: So an important limitation -- the
24 way they describe it is much broader than we think is
25 warranted. But nowhere in the specification or in the file

1 history does the patentee equate BONATH with "in close
2 proximity to the brainstem."

3 So in the specification all over the place, they
4 talk about different areas to apply it, right? Upper
5 posterior cervical area on the side of the head; a
6 relatively hairless area on the patient's head or neck.

7 Interestingly here, I don't think it's
8 particularly clear what we're referring to when they say
9 preferably this is a relatively hairless area of the
10 patient's head and/or neck.

11 In AfGin's responsive brief, they say this
12 sentence modifies "headache region" and not "close
13 proximity to the brainstem."

14 There's another one, "base of the neck." Now,
15 this is interesting, because this is what we tell our
16 customers or our patients to do, apply to the base of the
17 neck, the base of the neck being the bottom of the neck.
18 But that was in there.

19 Posterior cervical area, on the same side as the
20 headache --

21 THE COURT: Let me back up for a minute.

22 Is -- Mr. Flaming, is the base of the neck C1 to
23 C4?

24 MR. FLAMING: Base of the neck is going to be a
25 disputed question in the case, because they do actuality

1 use that term.

2 THE COURT: "They" who? What do you mean
3 "they"?

4 MR. FLAMING: The -- RXpress, on the
5 prescription --

6 THE COURT: Yes. But I'm trying to figure out
7 what -- in the patent, what the meaning of that is.

8 MR. FLAMING: Yeah, the patent. So the patent
9 doesn't specifically say what "base of the neck" means.

10 If you read throughout the patent, most of
11 the -- basically what the patent uses the term to mean,
12 it's talking about the upper part of the -- the mid to
13 upper part of the neck.

14 So I don't believe -- this is not a definition
15 of -- what he's got on the screen right now is not a
16 definition of "posterior cervical area." And when you look
17 at the actual studies -- and I'm using that a the whole
18 term -- the studies say where the patients were told to
19 apply it. So one reading the patent would look at the
20 actual declaration of the inventor and see a more specific
21 use of what he means by this term.

22 The patent uses it less -- more colloquially.

23 THE COURT: All right. Thank you.

24 MR. EMERSON: We don't think there's any way the
25 base of the neck can be in close proximity to the

1 brainstem.

2 THE COURT: Well, it seems -- I mean, I thought
3 we had agreed that one means the top and one means the
4 bottom.

5 MR. EMERSON: I agree. I think that's -- and I
6 think that's just standard English.

7 THE COURT: All right. Go ahead.

8 MR. EMERSON: "Posterior cervical area on the
9 same side as the headache, rub it onto the skin at the back
10 of the neck."

11 And then here we have "back of the neck at the
12 hairline." This shows up again for the first time in
13 Dr. Aung-Din's declaration dated I believe it's January the
14 4th of 2010. Yeah, it's right there, so I don't need to
15 turn and ask Mr. Chiarizio what that date was.

16 So in his declaration -- and this is where
17 BONATH comes from -- again, it's not in the patent
18 anywhere -- he uses BONATH to describe where they are --
19 where his patients were instructed to apply the cream. He
20 uses BONATH. He also says "mid posterior cervical area at
21 the hairline." So we're talking about the middle of the
22 back of the neck there.

23 THE COURT: But middle, in that context, we're
24 talking about measured vertically?

25 MR. EMERSON: Yes, Your Honor. Yes, Your Honor.

1 THE COURT: And if we were talking about
2 measuring this horizontally, it would be -- for these
3 purposes, roughly equivalent to where the spine is, the
4 middle of your --

5 MR. EMERSON: That's right.

6 THE COURT: -- of your neck --

7 MR. EMERSON: That's right.

8 THE COURT: -- measured horizontally.

9 MR. EMERSON: And to be clear, there was some
10 dispute in AfGin's briefing about whether -- you know,
11 whether we contended it had to be on the very, very back or
12 you could apply it to the sides. "The sides of the back of
13 the neck," we think, would be covered under any
14 construction if you could construe it, which we think it's
15 indefinite. So it's not limited to just the center line,
16 right? There's some area on the back of the neck, that
17 it's going to extend from side to side.

18 It's not the side of the neck. The patent
19 doesn't talk about applying to the side of the neck or the
20 front of the neck or any other part of the neck, other than
21 the back of the neck. But that back of the neck will have
22 some width to it.

23 So we have lots of different examples of the
24 back of the neck. And they never say what "in close
25 proximity to the brainstem" is, and they never tie that to

1 BONATH or anything else like that.

2 And the reason we think this claim term is
3 indefinite, because it is intrinsically unclear or actually
4 contradictory internally to say the back of the neck in
5 close proximity to the brainstem, because none of the neck
6 is in close proximity to the brainstem.

7 So they've chosen to construe the claim as
8 meaning BONATH, or back of the neck at the hairline, and
9 including from -- from roughly C4 up to C1. So they're
10 defining the hairline to be starting, I guess, somewhere
11 around C4 and then going up to the top of the neck. This
12 is just one of many examples that the specification and the
13 file history give us.

14 But the patentee didn't say at the hairline.
15 Not in the specification, not in the claims. And so we
16 assume that he chose his words carefully. In fact, this
17 term, this added term of "in close proximity to the
18 brainstem" was added some six years into the prosecution
19 process.

20 So "in close proximity to the brainstem" must
21 mean something more than simply posterior cervical area.
22 And as we'll see, the inventor equated BONATH with
23 posterior cervical area over and over again.

24 Here's in the response to the office action --
25 this is Slide 24 -- and this is the attorney's argument

1 where he talks about the posterior cervical area of the
2 human patient, also referred to by the inventor as the back
3 of the neck at the hairline. So he's equating "back of the
4 neck of the hairline" to "posterior cervical area" broadly.

5 THE COURT: Go back for a minute.

6 You've conceded from the beginning that
7 "posterior cervical area" means the back of the neck.

8 MR. EMERSON: That's right.

9 THE COURT: So what is -- so "at the hairline"
10 has to be adding something. Back of the neck is -- can be
11 well below the hairline.

12 MR. EMERSON: Back of the neck could be well
13 below the hairline.

14 THE COURT: So --

15 MR. EMERSON: So really the point is, he doesn't
16 equate BONATH to "back of the neck in close proximity to
17 the brainstem." He never goes that extra step.

18 I agree with you that hairline does add
19 something, but what it doesn't add is "next to the
20 brainstem." And he never said that and his attorney never
21 said that. Everywhere they equated the term BONATH with
22 something in the claims, it's "posterior cervical area";
23 not "posterior cervical area in close proximity to the
24 brainstem."

25 THE COURT: Well, I apart from what I think you

1 pointed out in your briefing, that hairline is not terribly
2 clear because the hairline is going to -- the location of
3 hairline on someone's neck, excluding counsel over there,
4 is going to vary by race, gender, et cetera. But it's
5 going to be clearly above the bottom of the neck. How far
6 up the spine we don't know.

7 MR. EMERSON: Yes, Your Honor.

8 In fact, I would say even if you adopted their
9 construction, which I'll urge you not to do for many
10 reasons. But even if you did, our "base of the neck"
11 instruction, we would argue, couldn't possibly infringe
12 that either.

13 THE COURT: Well, I guess, let me ask that
14 question. That's sort of the punchline.

15 Mr. Flaming --

16 MR. FLAMING: Yes, Your Honor.

17 THE COURT: -- are you claiming "the base of the
18 neck"?

19 MR. FLAMING: No.

20 THE COURT: Okay. All right.

21 MR. FLAMING: But what that means -- and I'm
22 not -- first of all, by making that -- let me make two
23 qualifications to that.

24 Number one, I'm not discussing it the way it was
25 used in the patent in one example. You'll see that

1 inventors don't always write things as though they're
2 writing a dictionary definition for a Court. But I'm not
3 going to delve into specifically what the inventor may have
4 used it at one time. But as we would use it, and as they
5 would probably agree, if it means the bottom of the neck
6 and the patient who gets the instruction interprets it that
7 way and the patient only applies it at, for example, the
8 clearest case, C7, then we would not say that's covered by
9 the patient.

10 THE COURT: Well, if they tell a patient to
11 apply it at the bottom of the neck and the patient applies
12 it up their nose, that's not their responsibility.

13 MR. FLAMING: Well, this would be an issue --
14 I'm not prepared yet to talk about infringement. But I
15 will say, as a preview of what we expect to argue, that
16 there's a substantial amount of cream going on the neck.
17 And I've got an example of this as we get into it.

18 But it's very -- it will be a question of fact
19 as to where that cream ends up going, okay?

20 THE COURT: Okay. But if -- if they tell a
21 patient to apply it at the base of the neck and they do
22 apply it only at the base of the neck, are you claiming
23 that that would be infringing?

24 MR. FLAMING: If they tell the patient -- let me
25 give a clear example. If they say, "Patient, apply it only

1 at C5 to C7 and nowhere else above that," then I couldn't
2 claim infringement on that. But the meaning of these terms
3 and how patients use them will be an issue in the case.
4 That's why I'm qualifying it.

5 THE COURT: Okay.

6 MR. EMERSON: I would dispute that. It's not
7 what the patient thinks. Again, this is an indirect
8 infringement case, Your Honor, and that's what their
9 infringement contentions say. It's all about inducement
10 and contributory.

11 Those require specific intent. And it's not the
12 patient's intent; it's our intent. We're the accused
13 infringer here, all right? So "base of the neck" we think
14 means what it means.

15 Now, if somehow a patient might mistake that and
16 say "base of the neck, that must mean at the base of my
17 skull" or if they applied it somewhere else, or they take
18 more of it and rub it all over the place, that's not our
19 problem, as you alluded to, Your Honor.

20 THE COURT: Well, we'll come back to this. But
21 as I understand basic anatomy, the base of the neck cannot
22 include C1 through 4.

23 MR. EMERSON: I agree.

24 THE COURT: And if it can't include 1 through 4,
25 I don't know how the direction to apply the cream at the

1 base of the neck can infringe when you're only claiming 1
2 through 4.

3 There's a question about whether "in close
4 proximity to the brainstem" goes all the way down to 4, but
5 it certainly can't go below 4. And the base of the neck, I
6 think, is below 4.

7 So we'll come back to this. I'm getting a
8 little bit ahead of myself. But I have that concern going
9 forward.

10 All right.

11 MR. EMERSON: So do we, Your Honor.

12 THE COURT: Go ahead.

13 MR. EMERSON: Further to the point I was making
14 before, which is BONATH was never tied to close proximity
15 to the brainstem. The test that Dr. Aung-Din described in
16 his declaration is at least in part reported in the
17 specification of the patent application at Examples 7 and
18 8.

19 And so you look at an Example 8. Example 7 is
20 just about the formulation. Example 8 is where they apply
21 it. Example 8, they talk about rubbing the gel into the
22 skin on the back of the neck, without specifying on the
23 back of the neck in close proximity to the brainstem or the
24 top of the back of the neck or really even at the hairline;
25 just says at the back of the neck.

1 So consistently in his declaration he talks
2 about "the back of the neck at the hairline." He refers to
3 it as "the mid posterior cervical area at the hairline."
4 Never mentions anywhere "in close proximity to the
5 brainstem."

6 This is something that the term included the
7 added limitation "in close proximity to the brainstem" for
8 some year-and-a-half about before that. He could have said
9 that BONATH -- when I say "close proximity to the
10 brainstem, I mean BONATH." He doesn't say that. He simply
11 equates that with the back of the neck or with the mid
12 posterior portion of the neck.

13 Okay. Now, the patentee -- Dr. Aung-Din, in
14 another example, he knew how to use the term "in close
15 proximity to the brainstem" when describing these examples.

16 Example 6 -- and Example 6, which is in the
17 specification, the patients were told to apply the
18 sumatriptan formulation to the posterior cervical area in
19 close proximity to the brainstem.

20 Now, this is not explained or defined anywhere
21 in the patent specification or anywhere else, but he knew
22 how to use the phrase, he knew how to instruct his patients
23 to use the phrase. And this is in Example 6, which is not
24 part of his declaration. Example 8 is part of his
25 declaration. And in Example 8, it's just the back of the

1 neck. So again, there's no tie between BONATH and "close
2 proximity to the brainstem."

3 These are the words he chose. He didn't say
4 "all over the back of the neck"; he didn't say "at the
5 hairline." He didn't say anything else. Very specific.
6 And those terms were added to the claim in 2008.

7 Here's another issue we have with their
8 proposal, Your Honor, is we just noted Dr. Aung-Din used
9 the term "back of the neck at the hairline" consistency.
10 He didn't say "at or near the hairline."

11 So as you alluded to a few minutes ago, we don't
12 think hairline is very helpful to -- to define the claim
13 term, because the hairline can be different on different
14 people. Like you said, your sex, your gender, your
15 haircut. I can tell you when I was in the Navy, my
16 hairline was higher on the back than it is today.
17 Mr. Chiarizio has no hairline. You have a different
18 hairline than we have. So that's one problem.

19 Defining the term with relation to something
20 that changes person to person is not very helpful. And
21 then when you add "or near," you're adding another area of
22 uncertainty here.

23 How near is near enough to the hairline?

24 Let's talk about this C4 -- C1 to C4 language.
25 We don't think that they are using this terminology

1 properly. In the declaration, he's talking about C1 to C4
2 nerves and not C1 to C4 vertebrae. And those are different
3 things. The nerves come out of the vertebrae -- out of the
4 top, although there's nothing in the record to tell us
5 where exactly these -- these nerves are in relation to the
6 neck or the vertebrae. But the nerves are different than
7 the vertebrae. That's just a figure showing the C1 to C4
8 nerves and what areas that they enervate.

9 And this is back to the earlier point. We have
10 lots of different hairlines, lots of different people.
11 It's simply not a helpful marker for anyone.

12 THE COURT: Really? Where do you go to get this
13 stuff, Mr. Emerson?

14 MR. EMERSON: Mr. Chiarizio is a master of
15 Google and Google images.

16 THE COURT: All right.

17 MR. EMERSON: So we respectfully submit that the
18 term is indefinite, because it doesn't make sense
19 intrinsically. We don't agree with their construction,
20 because they never once tied BONATH to "close proximity to
21 the brainstem." It's not in close proximity to the
22 brainstem. And BONATH is itself an unclear term, because
23 it varies by person. And then adding "or near to" adds
24 another area of dispute potentially.

25 However, if Your Honor is inclined to construe

1 the term, as we discussed earlier, we think "posterior
2 cervical area in close proximity to the brainstem" means,
3 in English, back of the neck at the very top or posterior
4 cervical area up at the C1 vertebra.

5 In their responsive brief, AfGin states that we
6 concede that the C1 and C2 vertebra are in close proximity
7 to the brainstem. We don't concede that. What we're
8 saying is the closest part of the neck is up there at the
9 top. But we don't say that it's close. In the same way
10 that Hobbs, New Mexico, is the closest city in New Mexico
11 to Dallas, but if you've ever made that drive, you know
12 it's not close to Dallas. It is not in close proximity to
13 Dallas. But it is the city in New Mexico that is in the
14 closest proximity to Dallas.

15 So we would urge, Your Honor, if you're inclined
16 to construe the claim, construe it as being up
17 approximately at the C1 vertebra, at the very top of the
18 neck.

19 And let me point something else out here, too,
20 Your Honor. And I think this is important. I was
21 re-reading the file histories over the weekend and came
22 across this office action response. It's in the original
23 utility application. And this is before they even added
24 the language "in close proximity to the brainstem." And
25 there was a prior art rejection, and the inventor argued

1 over the rejection.

2 And let me just make an admission here. This
3 was not in our briefing. I missed this somehow during the
4 briefing, but I saw this as I was reviewing the file
5 history over the weekend.

6 And there are a number of paragraphs that talk
7 about the distinguishing the -- the claimed invention from
8 the prior art. And he concludes this way: "In sum,
9 delivery of a relatively high concentration of indole
10 serotonin agonist, e.g. Tryptan, to trigeminal nerve
11 nuclear regions (the occipital-upper cervical junction) is
12 believed by the inventor to alleviate the pain process.
13 That methodology is presently claimed and is believed to be
14 distinct and patentable over the prior art relied upon by
15 the Examiner."

16 So this was again on this January 22nd, 2007,
17 office action response. It is at AfGin's appendix at
18 Page 1572, and this slide is Slide Number 49.

19 Now, the occipital-upper cervical junction.
20 Cervical, of course, means neck; upper means upper.
21 Occipital -- the occipital bone is the bone there at the
22 bottom of your skull at the back. That hole there is in
23 the foramen magnum, which is the hole through which your
24 spinal cord goes. So your spinal cord goes up out of your
25 spine and up into your skull through that hole in the

1 bottom of the occipital bone.

2 So when the patentee distinguishes the prior art
3 by saying, "No, no, here's what we do; we deliver the drug
4 directly to the occipital upper cervical junction," the
5 upper neck/skull junction, which, Your Honor, is consistent
6 with our proposed construction -- and this is the file
7 history. Again, it should have been in the brief. I
8 missed that. But we think that's important.

9 THE COURT: Let me -- let me see that drawing
10 again.

11 All right. Thank you.

12 MR. EMERSON: And just for completeness, this
13 was an example of the claims that were at issue when they
14 made this argument.

15 They were talking about a headache region.
16 Originally they just had claims directed -- I believe
17 directed to a headache region, and then there were
18 dependent claims that further defined the headache region.
19 Again, this is going back eight years now or more.

20 In this claim, it says, "The headache region
21 being selected from the group consisting of the posterior
22 cervical area of said patient, the frontotemporal region of
23 the patient and both."

24 Now, the frontotemporal region would be your
25 temples and in the area of your forehead, which doesn't

1 seem to be consistent with his distinction over the prior
2 art, which is at the occipital upper cervical junction.

3 But the relevant language here is "posterior
4 cervical area of the patient." And again, at this point,
5 your Honor, they have yet to add the further limitation of
6 "in close proximity to the brainstem."

7 So back when -- the part of the back of the neck
8 they were talking about was just the back of the neck.
9 They said it's -- this drug is applied to the occipital
10 upper cervical junction. And that was before they even
11 added "in close proximity to the brainstem."

12 Your Honor, that's all I have.

13 THE COURT: All right. Let me just ask you the
14 same question I asked Mr. Flaming.

15 On Teva, do you claim that there are fact
16 questions for the Court?

17 MR. EMERSON: Not really.

18 There is -- for claim construction in this case,
19 generally, I don't believe there are in disputed fact
20 questions as it relates to claim construction, because the
21 only facts we brought in were facts relating to the anatomy
22 and head and spine, and I don't believe any of those are
23 disputed.

24 THE COURT: All right. Thank you.

25 Just so we're all at the same place, what the

1 Court is focusing on throughout this is "in close proximity
2 to the brainstem." I don't think the phrase "the posterior
3 cervical area of the human patient" is disputed.

4 We've skipped over "a topical formulation." Are
5 we coming back to that one?

6 Okay. All right.

7 MR. FLAMING: Your Honor, I'm going to move my
8 computer up here, if that's okay.

9 THE COURT: Sure. That's fine.

10 MR. FLAMING: Make it a little easier for us
11 all.

12 Okay. Am I on the screen?

13 THE COURT: You should be. I've done my part.
14 It may be that when you moved, you disconnected me. I
15 don't know how to connect --

16 MR. FLAMING: Here we go.

17 THE COURT: Okay. Thank you.

18 MR. FLAMING: All right. So as I mentioned
19 before, I'd like to start with where we find support for
20 our construction and then answer the arguments that they've
21 raised. And apart from the one they just made, I've got
22 them all answered, at least our response to them.

23 So as we're -- I want to highlight the claim
24 term, just to emphasize that this is -- the term we're
25 talking about is "applied to the skin at the posterior

1 cervical area."

2 THE COURT: Okay. Am I correct that you're
3 PowerPoint doesn't have page numbers?

4 MR. FLAMING: It does not, Your Honor.

5 THE COURT: Okay. It's --

6 MR. FLAMING: But I can tell you, I think, which
7 slide that I'm on.

8 THE COURT: Well, no. It's not that I can't
9 follow you; it's just that it makes the record murky.

10 MR. FLAMING: What I've done in the past is
11 we've linked up the slides with the transcript, and it's
12 fairly easy to do, so you'll be able to see next to the
13 transcript where we are. We've never had a problem with
14 it.

15 THE COURT: Okay. Well, I don't know anything
16 about that, how do to do that or whether there's going to
17 be a problem with that.

18 MR. FLAMING: Okay.

19 THE COURT: I'm going to do it kind of the
20 old-fashioned way and just say the pages as we go. And in
21 the future, I'd like you to number the pages.

22 MR. FLAMING: Yes.

23 THE COURT: It's helpful to me. If I drop these
24 on the way to my office, I've got to try to put them back
25 together. The cover page I'm not counting. "Overview" is

1 your Page 1.

2 Okay. By my count, we're on Page 17, and I
3 would suggest that you just submit a set of these that are
4 numbered. And this is a diagram of the head, neck and
5 spine.

6 MR. FLAMING: Yes, Your Honor. If you'll
7 indulge me for three seconds, I'll number these.

8 THE COURT: Okay. Excuse me just a second.
9 We're going to take a five-minute break in place here.

10 (Recess.)

11 THE COURT: All right. Thank you, Counsel.

12 MR. FLAMING: All right. So I'm now on Slide
13 17. And what I have is, I have an illustration of the head
14 next to the illustration that they have, that RXpress has,
15 which more clearly shows the vertebrae. I'm putting these
16 up so I can give you an illustration, an understanding of
17 what I'm talking about as I go through these.

18 I think we're past a lot of this, but
19 nonetheless, I'll run through this quickly.

20 The back of the neck can be upper and lower.
21 There can be a side and a side and a mid. And I think
22 we've agreed that the entire posterior cervical area would
23 include the sides of the neck and the full neck from C1 to
24 C7.

25 So -- so the question is does the patent give

1 one of ordinary skill in the art, for example, a
2 neurologist, the ability to figure out what "in close
3 proximity to the brainstem" meant.

4 And as Your Honor pointed out earlier, there's
5 no dispute "posterior cervical area" means back of the neck
6 region. It's defined in the patent. I have highlighted
7 here on Slide 19 the -- one part of the specification. The
8 "posterior cervical area (back of the neck region)." And I
9 also point out that in the same sentence, in the same
10 phrase, it refers to the side of the headache. So that's
11 clearly stated in the patent. And it's also not in
12 dispute.

13 It also - here's another for example that I put
14 on the next slide, and this is in our brief. The patent
15 goes on to say, if we refer to the posterior cervical
16 region -- and then it gets more specific. "Most preferably
17 applied to the back of the neck, preferably in close
18 proximity to or on the area of skin above the brainstem."

19 Now, here's where we say that there's no dispute
20 what that means. If you look at Dr. Moskowitz'
21 declaration, he says that this -- the closest area to that
22 portion -- I'm now on Slide 23 -- is right behind C1-C2.
23 So that is not -- the meaning of that is not in dispute.

24 When the patent is discussing what it means,
25 it's talking about something that's in close proximity.

1 That has extra meaning beyond the entire back of the neck
2 region.

3 And if you see, we have C1 through C7
4 highlighted here. I've -- I've numbered them. This is
5 Slide 26 -- or 25, I'm sorry. And you can see that that
6 includes basically from the upper part of the neck down
7 to -- most of the way, but not all the way to the shoulder;
8 blades where it ends.

9 The inventor -- now, this is a question of case
10 law. This is a question of how a patent is read. And I
11 want to stop and sort of give a general overview of the
12 process that has to be used here. What RXpress has done --
13 and I'll show this when I get to their arguments -- they've
14 had an expert talk about the general, plain meaning in the
15 abstract of the term "close proximity," and he says, "I
16 can't figure out -- I don't normally use that to refer to
17 anywhere." And that's an improper process for claim
18 construction. The process for claim construction is read
19 the patent, read the file history, and if they those don't
20 resolve something, then walk outside of it.

21 So what does the inventor say? The inventor
22 clearly refers to "back of the neck at the hairline." And
23 I'm going to highlight a lengthy description in his
24 declaration where he goes through this.

25 THE COURT: But what -- what term is the

1 inventor construing with "back of the neck at the
2 hairline"?

3 MR. FLAMING: The "back of the neck at the
4 hairline" term is used by the inventor to refer to the
5 claim term "posterior cervical area in close proximity to
6 the brainstem," the entire thing.

7 And there's a couple of ways you can see that.
8 I've highlighted the exact section of the -- of the
9 argument responding to the nonfinal office action on Slide
10 29.

11 THE COURT: Well, is the back of the neck at the
12 hairline -- well, let me just ask the question.

13 In your judgment, does "back of the neck at the
14 hairline" include C1 to C4?

15 MR. FLAMING: Yes. That's what the inventor was
16 referring to, the skin behind C1 to C4.

17 Okay. And so first let's start out -- counsel
18 made an argument that the lawyer was defining the words
19 "posterior cervical area" to mean just the back of the neck
20 at the hairline. But that's not -- if you read the whole
21 argument, that's not quite what he did.

22 Above that, it's clear he's referring to --

23 THE COURT: What page are you at now?

24 MR. FLAMING: I'm sorry. On Slide 29. And
25 that's referring to the September 8th, 2011, response to

1 the nonfinal office action. And I have the appendix cites
2 there, 72 to 73. So that is the inventor's lawyer.

3 And at first he says, "It is respectfully
4 submitted that the rejection based on the combination of
5 these references does not render the presently claimed
6 invention obvious, in part because none of these references
7 hint or suggestion...topical formulation administered
8 topically to the skin at posterior cervical area of a human
9 patient in close proximity to the brainstem."

10 So what he's talking about there, he's referring
11 to that claim term. This is how these are done. You talk
12 to the examiner, you say, "I'm addressing this claim term."
13 Then later on, he says in the same -- in the same
14 declaration -- I'm sorry -- the same response, "At the
15 posterior cervical area of the human patient, also referred
16 to by the inventor as the 'back of the neck at the
17 hairline.'"

18 Even though he doesn't use the words "in close
19 proximity to the brainstem," that's what he's referring to.
20 Because he's referring to the claim term as is clear from
21 the paragraph above it.

22 And if it's not clear from that, the inventor is
23 very clearly describing only a portion of the back of the
24 neck area when he refers to "back of the neck at the
25 hairline."

1 Okay. And that's --

2 THE COURT: Wait. Let me -- I want to get the
3 sequence down here for a moment. And I'm sorry, I asked
4 you this before, and now I don't remember the answer.

5 What is the record reason for the addition of
6 this "in close proximity to the brainstem"?

7 MR. FLAMING: The inventor narrowed his claimed
8 invention.

9 THE COURT: But what prompted that?

10 MR. FLAMING: I can't really know that, but the
11 inventor is the one thing that seems to be obvious from the
12 record was, the inventor had done a study and discovered
13 that -- at first he was trying to get, as counsel showed
14 you at the end of his argument -- he was trying to claim
15 the entire -- basically the entire head and neck.

16 And his study showed that really all of the
17 effects of this drug -- the most effective part was at the
18 back of the neck at the hairline. So he narrowed his
19 invention, which inventors can do. And that's part of the
20 reason they want to avoid prior art, but --

21 THE COURT: Okay. So he had two different
22 declarations, one in 2010 and one in 2007?

23 MR. FLAMING: There's one declaration from the
24 inventor submitted in different parts of the patent
25 application. And what I'm referring to here --

1 THE COURT: Well, let me clarify what I mean by
2 my question.

3 The declaration of January 4th, 2010, which is
4 appendix -- I'm not sure whose appendix, 203 -- but at
5 Page 29, there's a reference to a declaration of
6 Dr. Aung-Din filed December 3rd, 2007.

7 Were there two different declarations?

8 MR. FLAMING: Oh, I think that's referring to
9 the parent application, not the declaration.

10 THE COURT: Well, it refers to -- oh, I see. I
11 think you're correct. I see what you're saying.

12 So it is referring to this same declaration
13 filed in the parent application.

14 MR. FLAMING: That's correct.

15 THE COURT: Okay. So at the time of this
16 declaration in 2010, the additional language "in close
17 proximity to the brainstem" had been added already?

18 MR. FLAMING: That's correct.

19 THE COURT: Okay.

20 MR. FLAMING: And so this -- this is, again, the
21 lawyers' response to the patent examiner. And he attaches
22 that declaration of the inventor, which I'm now showing.
23 And I'm skipping to Slide 32.

24 And this is where -- now, the inventor is
25 describing to the patent examiner why he believes there's

1 something good here. And he describes his study. It says,
2 "Application to the back of the neck at the hairline." And
3 then he says, "The transdermal sumatriptan formula was
4 applied to the mid posterior cervical area at the
5 hairline," which is consistent with C1 to C4. And he gives
6 the study results -- I've shown them again on the next
7 slide, Slide 33, and that is forehead versus BONATH, back
8 of the neck at the hairline. And here's another example.
9 He goes on to say, Slide 34, "In comparison of compounded
10 sumatriptan, topical application at the forehead and at the
11 back of the neck at the hairline, the unique nature of the
12 BONATH anatomical site for this therapy provided" -- I'm
13 going to the bottom -- "provided faster relief and response
14 times and significantly more complete relief."

15 So from these it's clear he is -- as the
16 patent -- everyone agrees, we're all using the term
17 "posterior cervical area" to mean back of the neck region.
18 He has narrowed his area to what he calls back of the neck
19 at the hairline. That is the portion of the neck that he's
20 referring to here.

21 And you can see the next -- in Paragraph 24,
22 which is shown --

23 THE COURT: But your position is that I
24 should -- he doesn't tell us in this declaration what "in
25 close proximity to the brainstem" -- which is the term in

1 the patent -- means, and in the patent, he doesn't use
2 "back of the neck at the hairline," but I should just
3 construe those things to be the same, and so I should
4 construe "in close proximity to the brainstem" to mean
5 "back of the neck at the hairline"?

6 MR. FLAMING: That's correct. And we cite for
7 authority for this.

8 If the specification isn't clear on a disputed
9 issue, it's proper to refer to the file history. And, in
10 fact, one construing the patent should read the file
11 history and the patent. This is well established law.

12 THE COURT: Well, is -- does "back of the neck
13 at the hairline" cover C1?

14 MR. FLAMING: Yes.

15 THE COURT: Why?

16 MR. FLAMING: Well, because he says so. As I go
17 down the declaration, I'll point this out to you. He gives
18 a very specific explanation of what he means by that.

19 So here I'm moving down to -- now, this is --
20 this is his declaration. It is in the record at -- on
21 Pages 96 to 97 of our appendix. And I'm on Slide 36.

22 This is very -- I joke this stuff is written in
23 Klingon. It's for doctors and it's very technical. But
24 you don't need to understand every part of this to
25 understand what he's saying.

1 He goes through and he says -- and I've
2 highlighted a few words here -- "the superior cervical
3 sympathetic ganglion is located between the internal
4 carotid artery and the jugular vein of the ventral aspects
5 of the transverse processes of the second, third and fourth
6 cervical C2 to C4 vertebrae." And then he goes on to say,
7 "This also includes C1."

8 This is where he's talking about where he finds
9 the nerves that he's trying to hit with the drug. And it's
10 clear what he's saying here.

11 Then he goes on to Paragraph 26, which is the
12 next slide, Slide 37, "From the above, it is clear that the
13 upper cervical" -- and in parens, he says C1 to C4; that is
14 what he means by it -- "nerve function." And as you can
15 see, he's talking about the vertebrae. Yes, the nerves are
16 in the vertebrae. But he's referring to a location where
17 C1 to C4 vertebrae are -- "with peripheral nerve free
18 endings in the skin at the back of the neck," parens
19 "BONATH..." "These provide the feedback mechanism to the
20 brainstem." That's what he means.

21 He says, I can get to the brainstem with this
22 drug at the back of the neck at the hairline, because
23 that's where the key nerves are located. That's what
24 allows the drug to send a signal to the brain to calm down
25 the trigeminal nerve. That's what he's trying to do in his

1 patent with his invention.

2 And Paragraph 27 makes it even more clear. This
3 is the next slide, which is Slide 38.

4 "The trigeminal nerve specifically provides
5 innervation at C1 to C4 at the back of the neck as the,"
6 quote, "cervical component of its cervico-trigeminal
7 complex." And the rest of this goes on to say that's how
8 I'm reaching the brainstem; that's how I'm reaching the
9 brain to stop the trigeminal nerve from overreacting, which
10 is what's causing the migraine.

11 In this declaration, it is clear what part of
12 the back of the neck he's referring to. The patent is less
13 precise. It doesn't spell out C1 to C4. But anyone
14 reading -- anyone of skill in the art reading this
15 declaration would understand what he's talking about. He's
16 giving a very specific area.

17 So, in summary, the intrinsic record is clear,
18 the inventor provides a detailed declaration saying exactly
19 why application to BONATH is the only place that works, and
20 he specifically identifies the C1 to C4 cervical area --
21 that's the neck -- as the place where the relevant nerve
22 endings are located. It is consistent with the
23 specification, which doesn't use these terms as more
24 colloquial, but the patent specification does define
25 "posterior cervical" as back of the neck region, and then

1 it gives more specific areas. But one can see from -- and
2 the example I have here on Page 39 is -- "preferably in
3 close proximity to or on the area of the skin above the
4 brainstem."

5 And Dr. Moskowitz does not deny that the closest
6 area to the brainstem is C1 to C2. All of this is entirely
7 consistent with what the inventor said, and all of this
8 is -- most importantly, when one reviews the patent, the
9 intrinsic record is what's consulted. And if the intrinsic
10 record provides what you need to reasonably construe the
11 term, then there's no reason to look outside.

12 So let me address RXpress' arguments. I've
13 lumped them into three categories.

14 The first one is that there is no area of skin
15 in close proximity to the brainstem in the abstract. And
16 when Mr. Emerson said that the -- they were not relying on
17 Dr. Moskowitz for anything other than basic anatomy, they
18 were relying on him for that. And if they aren't, they
19 have no evidence to the contrary.

20 I've pulled a few pages of his report, and I'm
21 highlighting something here. I'm now look at Slide 43.

22 If you read Paragraphs 1 through 12 of the
23 Moskowitz report and try to find a mention of any part of
24 the patent or prosecution history, you won't. Paragraph 12
25 is where he reaches his conclusion that close proximity to

1 the brainstem cannot be construed. He says, "Based on
2 these basic understandings of human anatomy, the term is
3 indefinite."

4 So where are they getting this from? They're
5 getting it from an expert who did not -- who reached his
6 conclusions, according to his own words, based on basic
7 human anatomy and not by consulting the patent and file
8 history. Now, he does go on to talk about a couple of
9 places there. But that's not how he reached his conclusion
10 on close proximity.

11 Had he read the inventor's declaration and
12 looked specifically at the part that says, "This is why I,
13 Dr. Aung-Din, am applying the formula to the back of the
14 neck at the hairline, because that's where the nerves are
15 at C1 to C4," he wouldn't have had the inability to figure
16 out what he meant by close proximity.

17 And I've cited this in our brief. I'll just put
18 it up here again. This is the Phillips case, which is a
19 watershed case. Back in 2002, the Federal Circuit had gone
20 more toward starting with extrinsic evidence and then
21 looking to the patent.

22 And here the Federal Circuit said, "The court in
23 Texas Digital placed too much reliance on extrinsic
24 sources...it suggested a methodology for claim
25 interpretation in which the specification should be

1 consulted only after a determination is made as to the
2 ordinary meaning or meanings of the claim term in dispute."
3 And that is exactly how their expert reached his
4 conclusion.

5 But properly viewed, the ordinary meaning is
6 after reading the entire patent, and the prosecution
7 history is also part, as we cited that law to the Court,
8 too.

9 I want to point out one more thing with their
10 expert report. Dr. Moskowitz specifically refers to the
11 Aung-Din declaration in the file history. But nowhere in
12 his declaration does he even mention the discussion of C1
13 to C4, even while he's arguing for C1 to C2, which renders
14 his report incredible or unreliable, but certainly it
15 doesn't address the fundamental problem that it has, which
16 is he didn't read that or he didn't consider it.

17 RXpress also argues -- and we have this in our
18 brief. And I don't think Mr. Emerson was making as much of
19 a point of it as they did in his brief. But there was a
20 paragraph defining the headache region, and they make it
21 sound as though -- or RXpress makes it sound as though that
22 paragraph redefines "cervical" to include head or to
23 require a hairless area. But that's not what that
24 paragraph said. That was part of the specification before
25 the claims were amended. The specification doesn't change,

1 and I don't know why that is. My more experienced patent
2 counsel tells me that's just how it is.

3 But if you read that paragraph, which I have
4 highlighted on Slide 48, it's talking about the headache
5 region. And last part of it, talking about a relatively
6 hairless area of the patient's head or neck, is obviously
7 referring to the entire paragraph. Because it starts out
8 with defining the region as the head and/or neck, and then
9 it goes on to talk about trying to find a relatively
10 hairless area.

11 So we don't read that paragraph as saying
12 cervical is the head, according to the inventor. In fact,
13 he was clear in the other parts of the patent -- and I
14 think we're all in agreement -- that it's consistently used
15 to mean the back of the neck region as it's defined.

16 And as for relatively hairless area, well, if
17 you can get -- C1 to C4 does have a hairless area. So you
18 can apply that preferably in some part there.

19 And I just -- I've reshown the slide that shows
20 back -- posterior cervical area is defined back of the
21 neck. He's not redefining cervical as head.

22 So cervical means neck. It's consistently used
23 to mean neck. There is no lack of clarity on that point.
24 The only issue in dispute at this point is what does the
25 inventor mean, what does one of skill in the art reading

1 the patent and the file history, would they be able to
2 figure out what the inventor meant by -- not posterior
3 cervical area, but the portion of the posterior cervical
4 are that is in close proximity to the brainstem.

5 THE COURT: Okay. Are you -- I mean, I
6 understand what you're arguing, but I can't remember ever
7 having a case where the argument was, as your argument is
8 here, that the inventor is his own lexicographer, and he
9 means in close proximity to the brainstem to be C1-C4,
10 although he never says that. I have to put A with B with C
11 to get there. He never says -- because of this disconnect
12 between the declaration and the words in the patent, he
13 never -- he uses in his declaration "back of the neck at
14 the hairline."

15 MR. FLAMING: Right.

16 THE COURT: And in the patent, he uses "in close
17 proximity to the brainstem." And I have to -- for you to
18 prevail, I have to conclude that "back of the neck at the
19 hairline" means "in close proximity to the brainstem," and
20 without anybody saying that expressly, particularly him,
21 and then construe "in close proximity to the brainstem" as
22 he construes "back of the neck at hairline," a term that
23 doesn't appear in the patent.

24 MR. FLAMING: Yes. And I'd cite you to a case
25 on that. This is not uncommon. When claim construction is

1 reached, inventors are not usually defining their terms.
2 In fact, it's rare for me to find a definition in the
3 patent. They're often left without definitions. And the
4 challenge of claim construction is to read the patent and
5 the file history and figure out what the inventor is
6 talking about in the claim.

7 Here it's very easy to see what he's talking
8 about, because he describes in graphic detail why there is
9 a very specific area of the human body, back of the neck at
10 the hairline, where you reach the nerves with the
11 formulation. It's not -- it's not at all difficult to see.

12 And I'll point you to a case -- we cite
13 Rosemount versus Beckman Instruments. It's a Federal
14 Circuit case that's in the brief, 727 --

15 THE COURT: I have it.

16 MR. FLAMING: Okay. And that's an example. The
17 patent was challenged because it never defined "close
18 proximity," and the Court said it's not specifically
19 defined. That's not -- it says -- the words it uses are,
20 "To accept Beckman's contention would turn construction of
21 a patent into a mere semantic quibble and serve no useful
22 purpose," which is being a little bit casual. But what
23 they're saying is you're not necessarily going to find a
24 definition of the terms that are in dispute. So you have
25 to look at the patent and file history and figure out what

1 is the inventor talking about. Could somebody reasonably
2 construe what he meant by that.

3 And reasonably, he's very clear, he means C1 to
4 C4. And the All Dental Prodx case is another example. It
5 says if there's any lack of clarity in the specification,
6 the file history can and should be consulted. And that's
7 what we have here.

8 THE COURT: All right. Thank you.

9 MR. FLAMING: I think I'm only down to the last
10 argument to address, which is not -- it says "at" not
11 "near." And that's correct. He used the term "back of the
12 neck at the hairline," and we're asking for "back of the
13 neck at or near the hairline."

14 So how can we reasonably do that? Well, the
15 reason is, we're actually in effect asking for a
16 construction of what he means by "at," because that's the
17 term he's using.

18 And to avoid a very narrow strip on the back of
19 the neck, you can see the C1 to C4 area is more than just a
20 very narrow strip. But they made this argument in their
21 responsive brief, and so I --

22 THE COURT: You don't have a head in there or
23 anything, do you, Mr. --

24 MR. FLAMING: What?

25 THE COURT: You're not going to pull a head out

1 of your bag?

2 MR. FLAMING: No, Your Honor.

3 Let me just find my -- if I didn't leave it.

4 THE COURT: You know what, Mr. Flaming, I was
5 going to take a break at 11:00. We'll just take it now,
6 and we can look for what you're looking for.

7 We'll resume at 10 past 11:00. I'll hear from
8 you on your concluding remarks, and then I'll hear,
9 Mr. Emerson, your brief rebuttal. And then we'll move to
10 the next term.

11 Okay. Thank you.

12 (Recess.)

13 THE COURT: All right. Counsel, we'll pick up
14 with whatever you had in your bag of tricks.

15 MR. FLAMING: Get to it in a second. I found
16 it. These backpacks or briefcases these days have so many
17 pockets. I have lost my keys for a week and after
18 searching the pockets multiple times.

19 THE COURT: Well, let me know if you find my
20 keys.

21 MR. FLAMING: All right. So before we go to the
22 "at or near," I wanted to use the Elmo -- because this a
23 Markman hearing, not using the Elmo is bad -- there we go.

24 This is, I think, maybe an easier way to see all
25 of this. Pardon my handwriting. The lawyer's response in

1 the declaration submitted -- this is after the term "in
2 close proximity to the brainstem" had been added to the
3 brain. So they're arguing over this term. And the lawyer
4 is specifically referring to it, even though after that he
5 only refers to the posterior cervical area. But in the
6 first part, it's clear, as I mentioned earlier, he was
7 referring to this term.

8 The problem that you may be having is the
9 inventor himself never says "in close proximity to" means
10 this. So that's a challenge. It's not as easy as it would
11 be if he had. But that declaration is submitted in support
12 of the argument for why he should get the patent with the
13 claim term as it was. And if you look at the term he's
14 using, "back of the neck at the hairline," it is clear that
15 "at the hairline" is the part referring to -- linked to "in
16 close proximity to the brainstem." Why? Because
17 everyone's in agreement that back means posterior, and
18 that's -- and neck means cervical. So posterior cervical
19 area is the first part of this phrase.

20 The only thing that "at the hairline" could be
21 is "in close proximity to the brainstem." And that, in
22 conjunction with his declaration explaining why, this is
23 the only area of the human body where I can get the -- get
24 to the nerves the way I want to, would make it clear to one
25 of skill in the art that this is what the term means.

1 THE COURT: Well, as a -- I mean, it's a little
2 bit difficult to generalize, because the term "at the
3 hairline" is going to vary from person to person. But if
4 I'm just imagining my only hairline, that's not going to be
5 C1 or C2.

6 MR. FLAMING: Hairlines -- there is a part --
7 there will be hair over C1 to C2. The inventor is
8 requiring --

9 THE COURT: But "hairline" doesn't mean is there
10 hair. Presumably -- I interpret that to mean the bottom of
11 the line of your hair.

12 MR. FLAMING: It's -- that's one of the reasons
13 why I think -- and I'm going to say this in a minute.
14 That's one of the reasons why I think that he's using a
15 term kind of speaking to people, right, but he's very clear
16 as to what the specific area of the skin that he's talking
17 about is. And that's why he says C1 to C4 and explains
18 that's how you get to the nerves.

19 But, you know -- and the fact -- just to address
20 this point, we have this in our opening brief. There's a
21 2015 Federal Circuit case that discusses the fact that
22 human anatomy may vary, and the Court concludes that's not
23 enough -- the variations aren't so significant that the
24 claim was unable to be construed.

25 I can refer you to the -- I'll give you the

1 first name, but I'm sure you've read it. But it's the
2 Warsaw Orthopedic case. And it's talking, in fact, about
3 cervical.

4 So that's how we read this. That's how we think
5 the term can be construed. And certainly there isn't clear
6 and convincing evidence in the record that one of skill in
7 the art could not construe this as the Federal Circuit
8 instructs us to read claims and terms within patents and
9 the prosecution history.

10 Okay. So now we get to "at or near." And this
11 is the more fun part of my argument.

12 C1 to C4 is not a small area. So that's why --
13 we might get into an argument later over what does "at"
14 mean. But I looked at the claims again -- they raise this
15 in their response, and I looked back. Claim 9 depends from
16 Claim 1. So Claim 9 adds limitations to Claim 1, which
17 means Claim 1 must be at least as broad as Claim 9.

18 And Claim 9 says, "The method of Claim 1 further
19 comprising applying the formulation to an area of intact
20 skin in the range of about 20 square centimeters to about
21 60 square centimeters."

22 And I'm not a big guy, but I'm not tiny. And we
23 decided to figure out what would 60 square centimeters look
24 like. So we go out a ruler. And, Counsel, you're welcome
25 to check. Mr. Kappel did the measurements -- check this.

1 If it were only one centimeter deep, to get 60 square
2 centimeters, you'd have this, which can't work, because
3 it's beyond the neck. And if you go to 2 -- 2 by 30 is 60,
4 that still crosses over past my ears.

5 So you have to get down to 3 by 20 to even make
6 it. And in -- what we're talking about is a pretty large
7 area. So that's why -- that in conjunction with C1 to C4
8 is why we're saying "at or near."

9 The inventor does not mean just a thin line
10 right there. He's referring to a pretty big area of the
11 skin. But if "or near" is troubling to the Court, we are
12 prepared to accept a construction that says "back of the
13 neck at the hairline, parens, C1 to C4." We might tweak
14 the language a bit, but that's the general idea.

15 THE COURT: All right. Thank you.

16 MR. FLAMING: And I think that's it. That's all
17 I have, unless you have questions.

18 THE COURT: All right. Thank you.

19 Mr. Emerson, I'll hear you for a brief rebuttal.

20 What I want to hear from you is, I think the
21 argument that Mr. Flaming is making is that it all boils
22 down to the declaration of the inventor; you're right, the
23 inventor in his declaration doesn't talk about "in close
24 proximity to the brainstem" and the patent doesn't talk
25 about "back of the neck at the hairline," but that those

1 phrases mean the same thing, and they mean C1 to C4 because
2 the inventor says so.

3 MR. EMERSON: Well, I'm not sure that he says
4 so. He talks about the -- and I mentioned this earlier --
5 the C1 to C4 nerves, which are different from the C4 -- C1
6 to C4 vertebrae. And the C1 to C4 nerves go all over,
7 number one. Number two, again, he never ties "back of the
8 neck at the hairline" to "in close proximity to the
9 brainstem."

10 Now, you're right, he submitted this declaration
11 while the claims that were currently pending were limited
12 to "posterior cervical area in close proximity to the
13 brainstem." That is true.

14 THE COURT: Let me interrupt for just a minute.
15 I'm going to let you go fully, Mr. Emerson.

16 But what Mr. Flaming was doing on the Elmo was,
17 "Okay, Judge, there's posterior, back; there's cervical,
18 neck; the only thing left is in close proximity to the
19 brainstem, so what else is he talking about when he talks
20 about back of the neck at the hairline? He has to be
21 talking about that by the process of elimination. Even
22 though he doesn't make the express linkage himself, I am
23 supposed to, because it's clear from the context that that
24 has to be what he's talking about."

25 MR. EMERSON: Well, he -- correct, never says

1 BONATH equals in close proximity, never says that.

2 THE COURT: No, that's not --

3 MR. EMERSON: In fact, he says BONATH is
4 posterior cervical region. He says that over and over
5 again. His lawyer says that.

6 I've got, on the Elmo, Slide 29 from their
7 presentation.

8 THE COURT: Well, he -- and that's the page
9 where in the fourth line on the page that you're showing
10 me --

11 MR. EMERSON: That's right.

12 THE COURT: -- he says, "Posterior cervical area
13 of the human patient in close proximity to the brainstem."
14 And in the next paragraph shown there, he says, "At the
15 posterior cervical area of the human patient, also referred
16 to as the back of the neck at the hairline." And although
17 he's not being as precise as in hindsight he should have
18 been, it's clear that he's talking about in close proximity
19 to the brainstem, because why else would he be talking
20 about it.

21 MR. EMERSON: Well, we certainly would concede
22 that it's clear. When you look at the first paragraph, he
23 is saying that the -- the attorney is saying our
24 invention -- the prior art doesn't teach the claimed
25 limitation. He says that without any reference whatsoever

1 to the declaration or the tests that were run. And then in
2 the second paragraph, consistent with what Dr. Aung-Din
3 says, he says that "The posterior cervical area of the
4 human patient, also referred to by the inventor as the back
5 of the neck at the hairline."

6 I don't know how you could be more clear.

7 THE COURT: Let me interrupt for a minute.
8 Because everybody agreed from the get-go today -- and I
9 think it's the one fact on which there is no
10 disagreement -- is that posterior cervical area of the
11 human patient means the back of the neck.

12 MR. EMERSON: That's right.

13 THE COURT: So does that statement, out of
14 context, estop him in effect from arguing that "at the
15 hairline" means in close proximity to the brainstem?
16 Because if I interpret it the way you're arguing, "at the
17 hairline" has no meaning whatever. Because if he didn't
18 say that, it would mean exactly the same thing.

19 MR. EMERSON: I wouldn't say that it has no
20 meaning whatsoever.

21 THE COURT: Well, what meaning does it have?

22 He is -- he says, "At the posterior cervical
23 area of the human patient, also referred to as the back of
24 the neck at the hairline."

25 If he said "also referred to as the back of the

1 neck," what would be the difference between "also referred
2 to as the back of the neck" or "also referred to as the
3 back of the neck at the hairline."

4 You're arguing that "posterior cervical area" is
5 the back of the neck. I'm just trying to figure out what
6 your contention is about -- how is he narrowing, if he is,
7 the agreement we all have that posterior cervical area
8 means the back of the neck, by using "at the hairline" in
9 the context of just the words "posterior cervical area"?

10 MR. EMERSON: I agree with you. It is not
11 clear. It's not clear. And you would think that "at the
12 hairline" is some kind of limitation. And they're reading
13 that limitation as being from C1 to C4. But it's not
14 clear. And he says never says -- whatever it means --
15 whatever BONATH means, and they repeatedly use the term to
16 refer to just the back of the neck. Whatever it means, it
17 is never tied to "in close proximity to the brainstem."
18 That's number one.

19 And number two, I would say this, with respect
20 to the -- the declaration and the experiments that he
21 carried out.

22 Number one, he carried those out in 2002 and
23 2003, five years before they added the "in close proximity
24 to the brainstem" argument, okay, number one, or that
25 limitation.

1 And then number two, they're saying that we
2 applied it to the BONATH, which they're saying is from C1
3 to C4, fine. The claim is more narrow than that. The
4 claim is more narrow than BONATH. If you define BONATH to
5 C1 to C4 -- and they never tie that to "in close
6 proximity." Fine. So they ran this test; they applied the
7 drug to C1 to C4; and it worked great. It was surprisingly
8 great. That's how they got over some of the obviousness
9 rejections. But "back of the neck" is broader than but
10 encompasses "back of the neck next to the brainstem."

11 So the test covers, according to them, C1 to C4.
12 We don't disagree with that necessarily. That's fine. But
13 the claim is more narrow than that. And so that's why we
14 way say there's no reason, there's no justification in the
15 file history, not in the declaration, nowhere, to say
16 BONATH is in close proximity to the brainstem.

17 THE COURT: This part of anatomy I don't know.
18 This distinction that you're making between C1-C4 vertebrae
19 and C1-C4 nerves.

20 MR. EMERSON: Yes, Your Honor.

21 THE COURT: Is that something that I can see on
22 your diagram? I don't quite understand.

23 MR. EMERSON: I think we have some -- we have a
24 diagram that has -- no, not much. And that's part of the
25 problem, Your Honor, is the nerves different than the

1 vertebrae. The nerves are different things. They're
2 called C1 to C4, because they are -- I believe they are
3 rooted there. But they come up and out and over the top
4 and go off in different places.

5 THE COURT: So I have no idea about this. I
6 don't know what I'm talking about. But are you saying that
7 a nerve -- the end of a nerve rooted in C4, the end of that
8 nerve might be closer to C1?

9 MR. EMERSON: As far as I know, but there's
10 nothing in the record. That's why this reference to C1 to
11 C4 nerves, I think, is -- makes things even more unclear.

12 THE COURT: All right. And are you representing
13 to the Court that the declaration of Dr. Aung-Din never
14 refers to the vertebrae; C1 to C4?

15 MR. EMERSON: I don't believe so. Let's show --
16 not in the place that -- they're not referring to it in the
17 place that they're talking about, about the nerves.

18 THE COURT: There is a reference to the
19 vertebrae C2 to C4, in Paragraph 25, but that's just
20 locating where things are in the brain.

21 MR. EMERSON: They're talking about the superior
22 cervical sympathetic ganglion is located between the
23 internal carotid artery and the jugular vein on the ventral
24 aspect of the transverse processes of the second, third and
25 fourth cervical vertebra.

1 Then they talk about the roots arising from the
2 ganglion join the first and second cervical nerves, the
3 third and occasionally the fourth, C1 to C4. They're
4 talking about the nerves there.

5 THE COURT: Okay.

6 MR. EMERSON: And there's nothing tying the
7 nerves to the vertebra --

8 THE COURT: Okay. All right.

9 MR. EMERSON: -- as far as location goes.

10 Just to clear up a couple of things -- unless
11 you have any further questions about this particular issue.

12 I thought I heard early on that we concede that
13 the back of the neck includes the sides of the neck. We
14 don't really, that it's the side -- that the back of that
15 includes the sides, that you could have sides of the back
16 of the neck. The back of the neck is the back of the neck.

17 THE COURT: That's what I understood you to be
18 saying.

19 MR. EMERSON: We do not concede that C1 and C2
20 are close to the brainstem. Dr. Moskowitz doesn't concede
21 that. He says it's the closest to the brainstem in the
22 same way that Hobbs, New Mexico, is the closest New Mexican
23 city to Dallas.

24 He did read and reference Dr. Aung-Din's
25 declaration. He cited it. He quoted it. And Dr.

1 Moskowitz doesn't refer to the patent, but he refers to the
2 words used in the patent, namely "posterior cervical area
3 in close proximity to the brainstem," and just simply
4 applies -- and that is not otherwise defined in the patent
5 specification or in the file history, but he uses those
6 words along with the understanding in the medical field of
7 human anatomy to come up with his conclusion.

8 So I don't think it's -- the point that
9 Mr. Flaming made that he doesn't refer to the patent or the
10 file history at all is, number one, not quite correct.
11 Because he does refer to and cite and quote the
12 declaration. And secondly, he's referring to a particular
13 phrase in the patent, in the claims, that is not otherwise
14 defined, and just applying the basic knowledge of anatomy
15 to that to reach his conclusion.

16 So unless you have any further questions, Your
17 Honor, I'm done.

18 THE COURT: No. That's it. I do want to hear
19 from you, Mr. Flaming, just on this one issue, and we'll
20 move to the next term.

21 MR. FLAMING: Yes, Your Honor, I have a Slide
22 ready to go.

23 THE COURT: This nerve/vertebrae issue.

24 MR. FLAMING: Yes.

25 So what counsel said is not accurate. The

1 declaration is clearly referring to the location of the
2 vertebrae. And I have it up -- Paragraph 25 is a dense
3 read. It's very dense. But even if you don't know the
4 specifics of what the declaration is talking about with
5 respect to the nerves, the afferent nerves, the things
6 providing signals back into AFF -- you know, into the
7 brainstem, you know, this -- this paragraph says that the
8 nerves I'm trying to reach are located -- and you can see
9 it at the -- I've highlighted it -- I have to put my
10 glasses on. I apologize.

11 THE COURT: I'm looking -- I'm reading it.

12 MR. FLAMING: Okay. He's talking about the
13 vertebrae. He says the cervical C2 to C4 vertebrae. He
14 then goes on to say "this also includes C1." And then he
15 says, so therefore C1 to C4. That is the location of where
16 the nerves he's trying to reach are found.

17 Now, let me know when you're ready, because I'll
18 move on to the next slide.

19 THE COURT: I'm ready.

20 MR. FLAMING: The next slide says "From the
21 above, it is clear that the upper cervical" -- that means
22 the neck, C1 to C4 -- "nerve function, with respect to
23 peripheral free nerve endings in the skin at the back of
24 the neck, BONATH is..." Then he goes on to talk about his
25 afferent nerves again. He says that is the location of the

1 nerves I'm trying to hit. They're at C1 to C4 in the back
2 of the neck at the hairline.

3 It's --

4 THE COURT: Well, I guess -- I guess the point
5 you're making -- and I'll hear the last word from
6 Mr. Emerson on this before he makes the next argument -- is
7 it doesn't matter where the nerves end; it matters where
8 they begin. Because if you were attempting to instruct a
9 patient, "Apply this to the C1 to C4 nerves," you wouldn't
10 necessarily know -- how would you know where they were?

11 I mean, you'd be applying them at the base, not
12 at the terminus.

13 MR. FLAMING: Uh-huh. The nerves come out to
14 the skin, the skin is where you put it. It's at the back
15 of the neck at the hairline, C1 to C4.

16 THE COURT: Well, that's not quite the point I'm
17 making.

18 You're applying it in the area of the vertebrae,
19 because otherwise how do you know where they are?

20 MR. FLAMING: That's fair.

21 THE COURT: Because the vertebra is in a
22 specific location. You don't necessarily know where the
23 nerves come out. So you would be applying it to where you
24 could locate where the vertebrae was.

25 MR. FLAMING: Yes.

1 THE COURT: And at the vertebrae is at the base
2 of the neck.

3 MR. FLAMING: I'm not sure about the use of the
4 term "base," but yes, where the nerves end, the end of the
5 terms.

6 THE COURT: I thought that was an unfortunate
7 term as it rolled out of my mouth. The connection --

8 MR. FLAMING: Yes.

9 THE COURT: -- of the nerves to the vertebrae.

10 MR. FLAMING: Yes, the nerve endings, for lack
11 of a better term.

12 THE COURT: Well, the nerve endings might be the
13 other end.

14 MR. FLAMING: Well, they actually -- I had a
15 lesson on this recently from the doctor. They sort of end
16 in both places. A nerve is a way of communicating. So
17 there's a nerve ending actually at the back of the neck.
18 And that is where the sumatriptan, once it's released from
19 the formulation, it binds to those receptors.

20 THE COURT: And that is --

21 MR. FLAMING: But it's the same thing, what
22 you're saying.

23 THE COURT: That is, in effect, coincidental to
24 the location of the vertebrae?

25 MR. FLAMING: In effect, yes.

1 THE COURT: Okay. All right.

2 Okay. Very good. Thank you.

3 All right. Mr. Emerson, if you have a last word
4 about that, I'll hear it. Otherwise, we'll move on to the
5 next --

6 MR. EMERSON: Very quickly. Could you switch to
7 our screen, Your Honor?

8 THE COURT: Yes.

9 Trying to spice this up a little bit?

10 MR. EMERSON: That's right. Exactly.

11 Safe for work, marginally.

12 What we have on the screen, Your Honor, is
13 another shot from Stedman's. And it shows there at the
14 lady's belly, anterior, ventral, and on the back,
15 posterior, dorsal.

16 So ventral means the front. When you look at
17 Paragraph 25, they're talking about this synthetic -- or
18 rather -- I'm sorry -- the superior cervical sympathetic
19 ganglion located between the internal carotid artery and
20 the jugular vein on the inside of your neck.

21 On the ventral aspects of the transverse
22 processes -- the ventral aspects being the front or the
23 anterior. So now we're talking about on the inside of your
24 spinal column, at the neck.

25 So I'm not quite -- you know, he's just

1 describing where certain nerves are. I don't think anyone
2 would say that by applying a cream to the back of the neck,
3 you're getting to nerves on the inside of your throat. I
4 don't -- I don't think.

5 But what it comes down to, this is all -- this
6 is all unclear. We're asking questions about, well, where
7 are the nerves, right? How do they relate to the
8 vertebrae? He's describing the -- the sympathetic trunk
9 ganglia as being on the inside of the second, third and
10 fourth cervical vertebrae. But now we're going in a
11 completely different direction. It's not the back of the
12 neck, right?

13 And then in Paragraph 26, he goes on to talk
14 about -- again, this makes it more clear. It's upper
15 cervical nerve function. So we're talking about the
16 cervical nerves, which have free nerve endings in the skin
17 at the back of the neck.

18 Well, where are those free nerve endings? They
19 may start somewhere in relation to C1 to C4, but where are
20 the free nerve endings?

21 Again, going down this path of trying to define
22 "in close proximity to the brainstem," based on this
23 declaration, which doesn't do that, again, adds more
24 questions than I think is -- more questions than we need to
25 be addressing here. It's not that hard.

1 Ultimately no part of the back of the neck is in
2 close proximity, but there is a part of the back of the
3 neck that in is in the closest proximity, if any, and
4 that's the very top of the back of the neck. And that's
5 just a simple way to look at it without reference to nerves
6 and nerve endings and what part of the skin is enervated.

7 So to the extent Your Honor is disinclined to
8 find this case term indefinite, we would urge the simple
9 precise, easy-to-understand definition in English, which is
10 the top of the neck, which we can define by -- by C1.

11 THE COURT: Okay. All right.

12 MR. FLAMING: Your Honor, may I respond --

13 THE COURT: No. We can't go on forever. We're
14 going to take it as closed there.

15 All right. Next one.

16 MR. CHIARIZIO: Your Honor, Matthew Chiarizio
17 for RXpress.

18 I just want to start with kind of a quick
19 overview of the next three terms. We cover "rapid
20 delivery," "immediate release" and "topical formulation."
21 All three of those, the argument is basically the same.
22 These terms are clearly defined in the specification
23 explicitly defined, and the claim construction law on that
24 is quite clear.

25 We know that they are defined terms, because the

1 patentee spends a column-and-a-half of clearly defining
2 terms. There's a whole list of terms. "For purposes of
3 the present invention," the quoted term means; the quoted
4 term "is defined as"; the quoted term "is intended to
5 mean." These three terms all appear in that list.

6 The first one is rapid delivery. Here
7 technically the defined term is "delivers." The patentee
8 uses that term, "With respect to topical formulation, it
9 means that the formulation or system provides a mean
10 relative release rate or flux of the drug out of
11 formulation or system and through the skin of the patient."

12 All we're asking you to do is to pick up the
13 definition that the patentee clearly provided there and use
14 that to define the term "delivery."

15 THE COURT: What does that "mean relative
16 release rate or flux of the drug" mean?

17 MR. CHIARIZIO: We're not really sure. That may
18 be indefinite.

19 THE COURT: Well, I -- I try to think ahead.

20 MR. CHIARIZIO: At this point --

21 THE COURT: And I know there may be another step
22 between here -- maybe several steps between today and a
23 jury trial. But my effort is whenever I can avoid it, not
24 to have a vision of the jury looking back up here at me
25 with "say what?" Which I mean, they're going to be looking

1 at me with that expression if I give them this definition,
2 because I don't know what about six of the words mean.

3 You're just saying, Judge, it's defined; that's
4 their problem --

5 MR. CHIARIZIO: This is the patentee's choice.
6 We're just asking you to honor that.

7 THE COURT: All right. Do you want to take
8 these all together, Counsel, or do you want to take these
9 one at a time?

10 MR. FLAMING: Whatever --

11 THE COURT: I mean, I think the argument is
12 going to be essentially the same.

13 MR. CHIARIZIO: Ours is, yes.

14 THE COURT: Look at the specs, these are right
15 out of the specs.

16 MR. CHIARIZIO: That's essentially my argument
17 for all three of these, that's correct.

18 THE COURT: As to these three terms. And then I
19 think we have left "provides relief."

20 MR. FLAMING: Maybe I can suggest, this is the
21 way -- we're going to agree with them that taking the
22 definition from the specification is usually the right way
23 to go. We have some reasons why they wouldn't be applied
24 in this case that differ by each term.

25 THE COURT: Okay.

1 MR. FLAMING: So if his argument is the same for
2 each -- and generally I don't disagree with him -- we've
3 got reasons that we think it would make more sense to
4 construe the terms a little differently, but they vary by
5 term.

6 THE COURT: All right. Thank you. I want to
7 ask you a question, Counsel, because the "immediate
8 release," I would not be inclined to give that example. I
9 don't know that the law prohibits me from doing so, but I'm
10 not persuaded just on the briefing why I would give it.
11 And I would be inclined to just stop at -- if I give
12 essentially -- well, let me back up for a minute.

13 As to the word "immediate," is that a disputed
14 term, what that means as far as you're concerned? Is -- is
15 the phrase available within zero to about five minutes? Is
16 that disputed?

17 MR. FLAMING: We don't think the example should
18 be included in the definition. I think the --

19 THE COURT: Well, that leaves the jury to wonder
20 what the word "immediate" means.

21 If I -- if I'm a layperson sitting on that jury
22 and I don't have any guidance as to the amount of time, I
23 probably don't think five minutes is immediate.

24 MR. FLAMING: This is why our construction is
25 what it is. In the medical industry -- and it's used

1 consistently in the patent. You've heard of extended
2 release drugs. You take a drug, and instead of coming
3 out -- all drugs are basically this. There's a thing that
4 holds the drug, and then the drug is inside and it comes
5 out somehow, most of the drugs are.

6 So in the -- in the medical industry, there's
7 immediate and extended release. And under extended is
8 delayed and prolonged. And so this is just saying -- it
9 doesn't have -- those extended release or delayed or
10 prolonged release drugs are doing that for a specific
11 reason.

12 For example, you might want a pill that delivers
13 aspirin to your intestines, because your stomach doesn't
14 like aspirin. So they've got this coating that prevents
15 the stomach from digesting it until it gets into the
16 intestines at which point it can be digested and then
17 releases in the right place.

18 There are other things where you want a
19 sustained, long-term release of a drug. All this is saying
20 is it's an immediate release; there's no delay in the
21 release of the drug. That's the gist of what this
22 paragraph is saying.

23 And even though it is defined in technicalese
24 the jury is going to get it confused. A medical
25 dictionary, consistent with this, distinguishes immediate

1 from delayed release. It's not a question of a matter of
2 time. It's a question of does the formulation in this case
3 block or delay the release of the drug. And so the claim
4 only covers something that's an immediate release drug,
5 which makes sense, because you're trying to treat a
6 migraine and you don't want it to be delayed.

7 THE COURT: Okay. Do you have anything else you
8 want to say about that?

9 MR. CHIARIZIO: He said it's not a matter of
10 time, but I think this definition that the patentee, again,
11 chose makes it clearly a matter of time by putting in the
12 example using minutes, "within zero to about five minutes."
13 I think you get to the heart of it by asking what would a
14 jury think immediate means, and they provide the example
15 there. And I think for that reason, it probably should be
16 included in the definition.

17 THE COURT: Okay. What objection do either of
18 you have to the following construction: "Immediate release
19 means the serotonin agonist is available for immediate, not
20 delayed or prolonged, absorption upon application of the
21 formulation"?

22 MR. FLAMING: Good for us.

23 THE COURT: What I've changed of yours is to
24 take out the parenthetical "available within zero to five,"
25 and I've taken out the three words "topical formulation

1 where," because I'm only defining "immediate release."

2 So I will read it again.

3 "The serotonin agonist is available for
4 immediate, not delayed or prolonged, absorption upon
5 application of the formulation."

6 MR. CHIARIZIO: I think that still ignores the
7 sort of issue of jury confusion. What does "not delayed or
8 prolonged" mean? And there again, they use time. I think
9 time is clear to the jury, and that's why we like the
10 example that's included there.

11 THE COURT: Okay. All right. That's going to
12 be the instruction I'm going to give. I think it's
13 consistent with the specification, and that's going to be
14 the instruction that I give.

15 All right. So that one is resolved.

16 I'm going to take under advisement the issue
17 we've spent most of the day discussing and will resolve
18 that later. But this one I'm going the way I just said.

19 MR. CHIARIZIO: Okay.

20 THE COURT: Okay. So rapid delivery.

21 MR. CHIARIZIO: For rapid delivery, we have
22 simply taken the exact definition that is provided in the
23 specification.

24 So if --

25 THE COURT: Okay. Let me hear from you on that,

1 Counsel. And, again, you want me to give them ordinary
2 meaning, which of course "mean relative release rate or
3 flux of the drug" doesn't have any ordinary meaning to
4 them.

5 MR. FLAMING: Right. Let me tell you why we
6 don't like this. It's written in technical terms again,
7 and so here's -- here's what --

8 THE COURT: It's written in technical terms, and
9 I don't -- I don't know what it means. I don't know what a
10 mean relative release rate or flux means.

11 MR. FLAMING: Okay. So if you -- I better put
12 my laptop -- I have an actual animation for this.

13 THE COURT: All right.

14 MR. FLAMING: So here's all that means. And if
15 you read the words after hearing this, you'll see it.

16 Drugs are -- the drug inside the formulation --
17 drugs don't behave as a human would. Drugs go any
18 direction. And they could go out of the formulation or
19 they could go into the formulation or just kind of sit
20 there.

21 And so what this says is that basically on
22 average, the drug is going out of the formulation. And the
23 one they use from -- I'll talk about the "through the skin"
24 in a minute. But if you watch my slide, I will show you
25 the animation that I made.

1 The red part is the drug; the green part is the
2 formulation.

3 See, most of those went out; one stayed in.
4 That's all this means.

5 So when you -- this term takes what is a pretty
6 straightforward claim term that could be given ordinary
7 meaning and makes it much more complicated, which is
8 generally not the direction that a claim construction
9 should go. It's a confusing-sounding way to say something,
10 but that's what it means.

11 THE COURT: Well, how do I get there?

12 MR. FLAMING: It's -- you have to read the
13 words, unfortunately. That's best we've got. If you read
14 it again, "The mean relative release rate or flux" -- so
15 the release of the drug out of the formulation and through
16 the skin of the patient. "Out" is the keyword there. You
17 have to get the drug out.

18 THE COURT: Well, I get "release of the drug out
19 of the formulation." What I don't get are "mean,"
20 "relative" and "flux." I don't know what those terms mean.

21 MR. FLAMING: Okay. Mean is average. Relative
22 release rate would be in or out.

23 But you can also -- if that's confusing, and it
24 is -- well, it's confusing to me. But let's look at the
25 claim. And then in the context of the claim -- if you'll

1 bear with me, give me a second, I'm going to switch back to
2 the Elmo.

3 Okay. Bear with me while I look for the term.

4 Okay. I'm going to zoom in a bit. There it is.

5 So here's what the claim says. It says,
6 "Topical formulation comprising the sumatriptan" -- that's
7 the drug we're trying to get into the skin -- "in an
8 immediate release topical vehicle" -- that's the
9 formulation -- "providing rapid delivery of the
10 sumatriptan" --

11 THE COURT: I can't see what you're --

12 MR. FLAMING: Oh, sorry.

13 "Providing rapid delivery" --

14 All right.

15 THE COURT: As long as you get that focused, I'm
16 okay.

17 MR. FLAMING: "Rapid delivery of the sumatriptan
18 for immediate absorption."

19 Just by looking at the claim, it's clear what
20 it's saying. It has to deliver the sumatriptan out of the
21 formulation so that it can be absorbed at the skin. So I
22 don't see why we would need to use this technical
23 definition when the claim term is clear.

24 There's no -- and I doubt there would be a
25 dispute on this term anyway. I can't imagine that RXpress

1 would say that its formulation does not deliver its drug
2 for absorption. We might argue a bit over rapid, but
3 theirs is immediate release as well.

4 So that's why we don't like this construction.
5 If we have to have this construction, we'll have to have an
6 expert talk about it. But once you read this and
7 understand the context and then look at the claim term,
8 it's clear what they're saying. And the claim term
9 doesn't, in our opinion, need to be turned into this --
10 this thing.

11 So that's our position on it, anyway, Judge.

12 THE COURT: So you're saying, essentially, that
13 the words "mean," "relative," and "flux," are completely
14 irrelevant to the interpretation of this term? In other
15 words, if I said "rapidly providing a release of the drug
16 out of the formulation," that would be an accurate
17 interpretation of this?

18 MR. EMERSON: No. The reason why this phrasing
19 is used is, mean relative release -- and I believe flux
20 is -- let me consult with my co-counsel now.

21 Okay. Well, the reason why it's said this way
22 is that the drug can stay in or go out. So that's what
23 it's talking about when delivers. So on average, the drug
24 has to leave the formulation. That's where mean comes in.
25 The average relative -- meaning does it go or out --

1 release. Rate or flux, which is the pace at which the --
2 or the change of the drug out of the formulation and in
3 through the skin of the patient. And that's a separate
4 issue. But that's what those words mean.

5 Because the reason why that's confusing is, it's
6 not obvious, until you think about it, that the drug might
7 not leave the formulation. So the -- and some of is not
8 going --

9 THE COURT: The drug might not what?

10 MR. FLAMING: Leave the formulation.

11 THE COURT: Need?

12 MR. FLAMING: I'm sorry. Leave, exit.

13 THE COURT: Okay.

14 MR. FLAMING: And so that's why -- in fact, some
15 of it won't. Some of the drug will stay in the
16 formulation.

17 So when you say delivers -- and that's
18 actually -- this isn't the claim term. But delivers, what
19 you mean is that the formulation has to let the drug, on
20 average, go out. It's just a technical way of saying that.
21 But it takes into account the fact that the drug doesn't
22 always do what you want it to do. I hope I'm making that
23 clear.

24 THE COURT: Okay. All right. Anything else on
25 that one, Counsel?

1 Go ahead. Are you finished with that one?

2 MR. FLAMING: Unless -- the reason we don't
3 include "through the skin" is the actual term in the claim
4 is not "delivers." It's "rapid delivery of the sumatriptan
5 for immediate absorption at the posterior cervical area..."

6 So the term in the claim is actually "rapid
7 delivery of the sumatriptan for immediate absorption."
8 That's why this general definition of "delivers" is not
9 appropriate for the claim.

10 The claim says "release for absorption." So
11 it's -- the claim term is talking about letting the drug
12 out of the formulation to the skin so that it can be
13 absorbed at the skin. That's why we don't think that's
14 appropriate as a definition either.

15 THE COURT: All right. I'll hear from you,
16 Counsel, if you want to add anything on that one.

17 MR. CHIARIZIO: In any case, you said at the
18 outset, we're not necessarily here to decide
19 indefiniteness. We're just here to construe the claim
20 terms.

21 I think that the claim construction law is
22 clear, when the inventor defines a term, that definition
23 governs. That's all we've done here. We pulled the
24 definition verbatim from the specification. This is the
25 definition the inventor chose. This is what he clearly

1 intended this term to mean at the time of the invention.
2 And that's all -- that's all we're doing is using that
3 definition.

4 THE COURT: Okay. I'm going to take this one
5 under advisement.

6 All right. Go on to the next one.

7 MR. CHIARIZIO: Can you switch the screen back
8 to this table?

9 MR. FLAMING: Our argument is basically the same
10 here. Once again, the patent defines "topical
11 formulation." We lift the definition of "topical
12 formulation" and use that as our explicit construction for
13 this term. So unless you have any questions, that's all I
14 have on that.

15 THE COURT: All right. Thank you.

16 MR. FLAMING: And our position on this term is
17 very simple.

18 The definition -- we're basically using this
19 definition, but we're using it in the context of the claim.
20 And again, this goes back to the claim construction law.
21 You have to consider the definitions in context.

22 The full wording of the definition is: "Topical
23 formulation includes, for example, ointments, creams,
24 lotions, pastes, gels, foams, viscous liquids, semisolids,
25 et cetera, which releases one or more drugs at a

1 predetermined rate over a defined period of time to a
2 defined site of application."

3 THE COURT: All right. Before you go any
4 further, let me just make sure. I think you-all agree,
5 although I find this odd, that it would be okay for me to
6 construe the claim using "et cetera." I don't think I've
7 ever done that, but you both had that in your construction.
8 And what that means is, there might be something like an
9 ointment, cream, lotion, paste, gel, foam, viscous liquid
10 or semisolid which we haven't thought of, but you all are
11 both okay with the use of the word "et cetera"?

12 MR. FLAMING: We're okay with that. I don't
13 think it will be an issue here, given that they have.

14 THE COURT: Okay. All right.

15 MR. FLAMING: Okay. So why do we leave out some
16 of the words? The reason is, for both of the things that
17 we leave out, is simple.

18 Claim 1 gives you -- the claims give you a
19 defined site of application. That's the posterior cervical
20 area of a human patient in close proximity to the
21 brainstem, which we've been debating. And they also give
22 you the predetermined rate, which is immediate release. So
23 that's why -- ours isn't inconsistent with the definition,
24 and we could include it all in the claim as the definition,
25 but it would be more confusing.

1 The claim already defines -- it narrows that to
2 a more narrow part of what the term means. So in effect,
3 it's using the same definition; it's just limiting it to
4 immediate release and delivering at this spot we've been
5 discussing. That's -- that's our position.

6 THE COURT: Well, I mean, to take Claim 1 -- I
7 mean, Claim 1 talks about immediate release; it talks about
8 rapid delivery. What does "at a predetermined rate over a
9 defined period of time" add to that?

10 MR. FLAMING: Nothing. It's -- we've already
11 defined it as immediate release. So there might be other
12 things encompassed by this general term that the inventor
13 is not claim ing in Claim 1. He's limited, immediate
14 release.

15 THE COURT: Okay. All right. I want to ask
16 that same question to you, Counsel.

17 What does that -- because the claim itself --
18 this one is a little bit different. The claim itself talks
19 about immediate and rapid delivery. I understand what the
20 specification says. But the topical formulation is --
21 isn't it just the cream, ointment, paste, et cetera -- what
22 does "at a predetermined rate over a defined period of
23 time" mean, other than "immediate release" and "rapid
24 delivery"?

25 MR. CHIARIZIO: I'm not sure that the

1 specification ties "immediate release" to -- is it the --
2 excuse me. Let me get the --

3 How do we know that the predetermined rate is
4 immediate release? Those are the same thing in that claim.
5 I mean, they're both used in the claims, but they're
6 separate terms. Both of those terms are defined
7 differently, in terms of "topical formulation" and
8 "immediate release."

9 I guess we're not willing to concede that the
10 predetermined rate necessarily is immediate release.

11 THE COURT: Well, in -- well, are you saying
12 that Claim 1, "a topical formulation" could mean something
13 that is released in 15 minutes?

14 MR. CHIARIZIO: Well, the term in the definition
15 is "predetermined rate over a defined period of time." And
16 so I'm not exactly clear that "immediate release" is
17 necessarily the exact same thing as "a predetermined rate
18 over a defined period of time."

19 THE COURT: Okay. Let me ask you one question,
20 Mr. Flaming.

21 Why would I include "to a site of application"
22 if I wasn't including "predetermined rate" and "defined
23 period of time"?

24 I mean, I think your argument essentially is the
25 topical formulation is the ointment, cream, et cetera.

1 What you do with it is the other part of the claim.

2 MR. FLAMING: Correct.

3 THE COURT: And not the topical formulation or
4 where you put it.

5 Why isn't the same question -- and it isn't
6 where you put it either. So I'm not following why you
7 would have me delete the reference to the rate and the time
8 but not the location.

9 MR. FLAMING: You're right. You sold me.

10 THE COURT: Love my job. It's so awesome when
11 that happens.

12 Thank you.

13 Okay. So the proposal of the defendant is
14 "ointment, cream, lotion, paste, gel, foam, viscous liquid,
15 semisolid, et cetera," period. And you want me to include
16 rate, time, site?

17 MR. CHIARIZIO: I just want you to adopt the
18 definition that the patentee chose. I haven't seen a case
19 where -- that says you are free to ignore the patentee's
20 very clear explicit, unambiguous lexicography. In fact,
21 all of the cases that I've seen point exactly the other
22 way. When there is explicit lexicography, the patentee's
23 definition governs. And that's all we're asking.

24 THE COURT: Well, I agree with that. But the
25 reason I'm hesitant in this case is because, for this

1 definition -- and if we were interpreting "transdermal
2 therapeutic system," it would be the same -- is -- well,
3 I'm not going to give that as an example. It might not be
4 a good example.

5 But the topical formulation, as this one reads
6 to me, is the cream, lotion, ointment, et cetera. And then
7 it's what does it do, not what is it. And that's why I --
8 I agree with your general philosophy. And my reticence
9 here is not because I think it's confusing, but I think
10 it's going beyond the definition of the term "topical
11 formulation" to tell us what then is going to be done with
12 it. And what's going to be done with it is defined in the
13 claim after the use of "topical formulation." So that's
14 why I'm hesitant.

15 Do you have anything that you want to add to
16 that?

17 MR. CHIARIZIO: I understand your point there.

18 And I think I would just say that the -- when it
19 starts with "which releases one or more drugs at a
20 predetermined rate over a defined period of time to a
21 defined site of application," that that is still part of
22 the definition. It's defining what it is and what it does.
23 And that's all part of the same sentence. "For purposes of
24 the present invention, a topical formulation includes"
25 these things which do this.

1 And so I think that the definition is a whole
2 package. It's being defined by what it is and what it
3 does.

4 THE COURT: All right. I'm going to go with the
5 more limited construction on this: "Ointments, creams,
6 lotions, pastes, gels, foams, viscous liquids, semisolids,
7 et cetera," because I think that the issues of rate, time
8 and location are expressed in additional words in the
9 patent, in the claims of the patent. And so I think there
10 is an unnecessary redundancy in the Court including that.
11 So I'm going to adopt that construction.

12 All right. So I've taken under advisement
13 "rapid delivery" and "in close proximity to the brainstem."

14 And the last one I have is "provides relief."

15 Did I skip something? Or is that it?

16 MR. EMERSON: I believe that's it, Your Honor.

17 THE COURT: Okay. And, essentially, the dispute
18 is this doesn't tell us anything about degree. The defense
19 wants "alleviates, makes better, feel better," but just a
20 little would be enough, it doesn't have to be complete, and
21 the patent uses the range of types of relief from initial
22 relief to complete relief. And that's your essential basis
23 for saying, well, it's indefinite; how much is enough?

24 MR. EMERSON: That's right, Your Honor. It's
25 indefinite as to the -- the extent of the relief, whether

1 it's just a little or goes all the way through complete
2 relief, no more headache symptoms whatsoever.

3 The type of symptoms that are being relieved,
4 either the headache itself or the side symptoms of
5 photophobia and nausea, for example. We don't know about
6 that. It doesn't say anything about -- it's not clear
7 whether the relief refers to that in the claim. And it
8 also is unclear as to what caused the relief.

9 I mean, relief anywhere, anytime is -- it's not
10 clear. It's just not clear the extent of it, the nature of
11 the symptom that's being relieved or the cause of the
12 relief. And for those reasons, we think this is
13 indefinite.

14 You said that this is a term of degree, right,
15 there's a degree of relief here. And we think that -- that
16 relief in this claim is a term of degree. And we find
17 those in lots of claims. And the courts have addressed
18 this idea of a term of degree. And I think that the recent
19 Nautilus cases are very, very instructive here on terms of
20 degree, like relief.

21 And if we could back up a little bit about the
22 Nautilus cases. If you'll recall in Nautilus, it was a --
23 a treadmill that you hold onto the handles and it would
24 calculate your heart rate. And there were electrodes on
25 the handles that had to be in a spaced relationship. And

1 the district court at first said "spaced relationship," you
2 know, that doesn't tell me how much space is enough, how
3 much -- what is the proper spacing here? This is
4 indefinite. The Federal Circuit said, well, you can figure
5 something out. I mean, it's not -- it's got to be a space,
6 any space. It's not indefinite.

7 Goes up to the Supreme Court. The Supreme Court
8 says, you're using the wrong test. The test isn't whether
9 you can construe it at all, but the test is whether it
10 provides reasonable certainty to a person of ordinary skill
11 in the art. So reevaluate it.

12 And so this is the case that I think is very
13 helpful, is the Federal Circuit case law on remand. And
14 they talk about a spaced relationship. We know what the
15 outer bound is, because these two electrodes have to be
16 within the width of your -- of a normal person's palm,
17 right? They've got to be there. So that's the outer edge.

18 The inner edge is -- it doesn't really make
19 sense. Because you could keep slicing the space in half in
20 perpetuity. And ultimately you get to something that is
21 essentially no space whatsoever. So there has to be a way
22 to figure what the appropriate space is.

23 And so the Federal Circuit looked at the file
24 history. And in the file history, in order to overcome
25 some prior art, the inventor submitted a declaration that

1 explained how one of ordinary skill in the art would
2 determine the proper spacing. And the proper spacing had
3 to do with canceling out some electrical readings from
4 your -- from your body.

5 But there was a way to do it. So -- so it
6 wasn't that you could look at a spaced relationship and
7 say, "Oh, well it's anything from the width of the hand to
8 virtually nothing." We have to be able to define that.

9 And the Federal Circuit found in the file
10 history the declaration from the inventor that explained
11 exactly how to determine what the proper spaced
12 relationship is.

13 And we have the same issue here, Your Honor. We
14 have a term of degree, namely --

15 THE COURT: I'm sorry. What was the end result
16 there?

17 MR. EMERSON: The end result -- that's
18 important. The end result in the second Nautilus case at
19 the Federal Circuit was it's not indefinite. It's not
20 indefinite, because the intrinsic evidence tells us how one
21 of ordinary skill in the art would be able to determine or
22 calculate the proper spacing.

23 THE COURT: That case is going to go back up to
24 the Supreme Court again. I'm looking for any case that
25 might beat my personal record in reversal in a single case.

1 MR. EMERSON: Don't know of any.

2 THE COURT: Thank you.

3 MR. EMERSON: But here are where the parallels
4 are, Your Honor.

5 In the Nautilus cases, we're talking about a
6 term of degree. And the Supreme Court and the Federal
7 Circuit talk about Seattle Box, which says you can use
8 terms of degree, they're perfectly fine, but somewhere in
9 the intrinsic record you've got to know how to determine
10 what the bounds are, all right?

11 With a spaced relationship, there were bounds,
12 the width of the hand, or really, you know, an
13 infinitesimally small space. And that wasn't -- and that
14 wasn't good enough.

15 Here we have a term of degree, "relief." And
16 we've those bounds. Those bounds are complete relief, no
17 more headache, no more nausea, no more photophobia, you're
18 perfectly normal and you're completely cured of this
19 migraine headache.

20 And on the other end is something completely
21 subjective, infinitesimally small degree of relief, so
22 small that who even knows if it's really relief.

23 So how is a person of ordinary skill in the art
24 supposed to determine at what level -- what level of
25 relief, what extent of relief, and what symptoms is

1 required by the claim.

2 THE COURT: Well, I'm not following why there
3 has to be a statement as to how much better you have to be.

4 If you -- if a product were marketed, and on a
5 scale of 1 to 100, if you had a terrible headache and it
6 was a 100 and you took a medication and as a result of
7 taking the medication you were at 99, people wouldn't buy
8 it, so it wouldn't be commercially successful, but it
9 provided 1 percent relief. Why does it have to provide a
10 threshold or datapoints as to the degree to which you feel
11 better? And when you're talking about a person's feeling,
12 how would you write something that was more specific than
13 "provides relief" or "alleviates pain"?

14 MR. EMERSON: Well, you could say that the
15 headache is gone or you could say that the -- that the
16 headache pain has been, you know -- it says that it's no
17 longer there or you're no longer nauseous or you no longer
18 have photophobia.

19 THE COURT: Well, if someone is at 100 of pain
20 and someone could take a medication that moved them from
21 100 to 50, that product may be commercially successful if
22 there's not another product that moves them from 100 to 0.

23 It just -- in the context of what is a
24 subjective kind of measurement that is not detectable
25 except by asking the patient -- there may be some physical

1 manifestations of a migraine, but I'm going to put those to
2 the side for a moment. Most of the symptoms of a migraine
3 are subjective to the patient. And others don't know how
4 the patient feels except for the patient reporting that.

5 So that's not the usual kind of measurement of
6 degree. How far apart are the electrodes on a treadmill is
7 quite a bit different from "do you feel better as a result
8 of taking this medication?"

9 MR. EMERSON: That's right.

10 And, Your Honor, that -- that raises a related
11 issue. And that is this is purely subjective.

12 I agree, this is a relative term, and it is a
13 lot harder to determine in an objective way what it is to
14 mean, particularly when you compare that to a spaced
15 relationship.

16 Another case that you should take a look at is
17 the Interval Licensing case.

18 THE COURT: Is that Judge Gilstrap's case?

19 MR. EMERSON: Was Interval Licensing Gilstrap's?
20 I don't remember.

21 THE COURT: Okay.

22 MR. EMERSON: But I believe this is right.
23 Interval Licensing was the case where they talked about
24 there being a purely subjective term, and if the purely
25 subjective term -- if it's purely subjective, it was held

1 to be indefinite. So here we have a case of like -- like
2 Nautilus, it is a term of degree. Unlike Nautilus, it is
3 not amenable to an objective range, like you say, 1 to 100,
4 or what-have-you, to be -- to be very precise. It's
5 like -- in that manner, it's like Interval Licensing, where
6 the Federal Circuit said this claim term is purely and
7 wholly subjective. And there I think, if I recall,
8 Interval Licensing dealt with the look and feel of a
9 webpage.

10 Right, the term there was "in an unobtrusive
11 manner." Well, that's completely subjective. And it was
12 held to be -- because it was completely subjective, held to
13 be indefinite.

14 THE COURT: And Court did not construe the term?

15 MR. EMERSON: I don't believe so, no. I don't
16 believe so. I could look at that. If I'm wrong, I'll let
17 you know.

18 THE COURT: You recognize -- I mean, the
19 Court -- I'll say this differently.

20 If I construed "provides relief" to "as
21 alleviates" as advocated as the alternative by the
22 defendant, then you're going to file a motion that that
23 term is indefinite, and nothing would keep you from doing
24 it. I pretty much gave you that opportunity to do so
25 conditioned on my finding.

1 MR. EMERSON: That's right, Your Honor. And we
2 very well may. But we think given this, like in Interval
3 Licensing, it is a wholly subjective claim term, that it's
4 going to vary from person to person.

5 THE COURT: I'm not disagreeing -- I'm not there
6 yet. This is the best example of what I said at the
7 beginning. I think it's your other case before me,
8 Mr. Emerson, where I couldn't construe a term because there
9 wasn't enough there for me to construe the term.

10 MR. EMERSON: Right.

11 THE COURT: So I found it to be indefinite, but
12 it was because I couldn't construe the term.

13 MR. EMERSON: Right.

14 THE COURT: If I construe this term "as
15 alleviates," you're not in any different position than you
16 are essentially arguing now. You're going to say
17 alleviates is completely subjective. What does that mean?
18 It could be a little teeny bit; it's a lot. It's
19 indefinite. You'd still be arguing that.

20 MR. EMERSON: I would do that.

21 THE COURT: All right.

22 MR. EMERSON: I would likely do that.

23 I think alleviates is just a synonym for
24 relieves.

25 THE COURT: Provides relief.

1 MR. EMERSON: And it just -- it doesn't add
2 anything. And it has the same problem, and that is it is a
3 wholly subjective term that's going to vary from person to
4 person, just like "unobtrusive manner" did in the Interval
5 Licensing case.

6 THE COURT: Okay. Very good.

7 All right.

8 MR. FLAMING: First of all, we don't think the
9 term requires construction. We think the term "provides
10 relief" is clear on its face and it can be evaluated. And
11 I'm surprised it's an issue. Because, in effect, putting
12 aside the matter of degree I'll get to in a second, RXpress
13 would have to take the position that the drugs -- the
14 formulation it's selling does not provide relief.

15 So what is their argument? I don't think I have
16 much to add --

17 THE COURT: I'm sorry. Say that again. I'm not
18 following you.

19 MR. FLAMING: Sure. They would have to take the
20 position that their product does not provide relief. The
21 patent is clear, they're not -- and here's the slide I'm
22 referring to. Slide --

23 THE COURT: I think they're arguing their
24 product does provide relief, in the sense that people in
25 common parlance use that phrase, but that doesn't mean it's

1 satisfactory for patent construction.

2 MR. FLAMING: Yes. Well, an ordinary -- the
3 case law is very clear on this. An ordinary term can be
4 perfectly acceptable. And if you look at what the inventor
5 did define relief to be, "When head pain and migraine
6 symptoms are first noted to be alleviated."

7 THE COURT: What page are you at now?

8 MR. FLAMING: This the results of a study.

9 THE COURT: Just give me --

10 MR. FLAMING: I'm sorry. I'm on Slide 33.

11 THE COURT: Okay. I got it. Okay. I'm with
12 you.

13 MR. FLAMING: And he distinguishes that from
14 what he calls response, which is when severe to moderately
15 severe pain and symptoms are relieved from the point of --
16 to the point of mild to none. Relief is first noted,
17 relief of symptoms.

18 Their point, I think, is stated a little bit
19 more succinctly. AfGin is saying "provides relief" means
20 any relief. And that just seems broad. But we've cited
21 plenty of case law. The fact that it's a broad term -- and
22 it is a broad term. It could be 1 on a scale of 1 to 100.
23 That's what the patent claims. It does not limit relief to
24 any degree beyond initial relief. It's fairly
25 straightforward.

1 And after the subjectivity point -- this is not
2 the kind of subjectivity that the cases they're citing talk
3 about. You know, those cases went to look back at the
4 prosecution history and the spec and didn't find what they
5 needed to answer the question. Here, you can look at the
6 file history and see very clearly what he's talking about.

7 How do you measure it? You ask the patient.
8 We've cited evidence to this effect. It's not countered.
9 There in is no way to determine if pain has been alleviated
10 without asking the question. There's no way to measure it.

11 So the only way you can do it is exactly how the
12 doctor did it. He asked them. He said, "Did you get
13 relief?" And that's in here.

14 And as for the subjectivity cases, the two they
15 cite are one call Datamize, which refers to the term
16 "esthetically pleasing." And the Court found that
17 effectively there was nothing in the prosecution history to
18 find that. And the second one, which we've talked about,
19 is the "in an unobtrusive manner that does not distract a
20 user of the display device, or apparatus associated with
21 the display device, from a primary interaction when display
22 device or apparatus" -- "with the device."

23 And the Court went on in the case -- the Court
24 went on to examine what was there in the file history to
25 say what does that mean, "unobtrusive manner," and found

1 numerous conflicting parts.

2 Here, there's nothing conflicting. Relief is
3 relief. Relief is initial relief. There's nothing that
4 says relief is limited in any way. So we think this is a
5 fairly straightforward construction. And I would be more
6 comfortable, in fact, with "provides relief."

7 THE COURT: You would be more comfortable what?

8 MR. FLAMING: Just leaving it as is. The term
9 doesn't seem to require construction to us.

10 If there is a need for defining it, I mean, the
11 inventor says, "When head pain and migraine symptoms are
12 first noted to be alleviated." Initial relief, that's what
13 he's talking about.

14 THE COURT: Okay. Anything else on that one?

15 MR. EMERSON: Your Honor, you had asked me the
16 question did they -- did the Interval Licensing court
17 construe the term. No, they did not. They did not
18 construe the term. They just found initially that it was
19 indefinite because it was wholly -- wholly subjective.

20 And we have the same situation here, that you
21 know, it's subjective. There are lots of examples of what
22 relief could be, but we don't know which of those works.

23 THE COURT: Okay.

24 MR. EMERSON: So that's our position, Your
25 Honor.

1 THE COURT: Okay. This one I'm taking under
2 advisement, but for a limited purpose. I'm going to read
3 these cases on subjective scope. And I'm either going to
4 conclude that it -- the proper construction is
5 "alleviates," or I'm going to conclude that I can't
6 construe it.

7 I'm very likely to construe it as "alleviates"
8 and let you come back to me on a Nautilus motion.

9 MR. EMERSON: Understood. Thank you, Your
10 Honor.

11 THE COURT: Okay. All right.

12 Anything else for us today?

13 Okay. Very good job. Thank you all very much.
14 I appreciate very good argument. I'll get back to you as
15 soon as I can.

16 Thank you.

17

18 (Proceedings concluded.)

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Dated this 24th day of September, 2015.

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